

UAB „Tradintek“

J.Jasinskio g. 9, LT-01111 Vilnius, tel. nr. (8 5) 2685427, fakso nr. (8 5) 2496084, registro tvarkytojas VI Registrų Centras, įmonės kodas 124942182, PVM mokėtojo kodas LT249421811

Lietuvos sveikatos mokslų universiteto ligoninei Kauno klinikoms,

PASIŪLYMAS

DĖL UROLOGINĖS ENDOSKOPINĖS ĮRANGOS PIRKIMO

2025.01.08 Nr. 250108/kk
Vilnius

1 lentelė

TIEKĖJO REKVIZITAI

Tiekėjo pavadinimas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/	UAB „Tradintek“
Tiekėjo adresas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių adresai/	J.Jasinskio g. 9, Vilnius
Įmonės kodas, PVM mokėtojo kodas	Įm.k. 124942182 PVM mokėtojo kodas LT249421811
Atsiskaitomosios sąskaitos numeris, bankas, banko kodas	
Įmonės vadovo pareigos, vardas, pavardė	Direktorius Tomas Mickūnaitis
Už pasiūlymą atsakingo asmens vardas, pavardė	
Už sutarties vykdymą atsakingo asmens pareigos, vardas, pavardė, el. pašto adresas, telefono numeris	
Telefono numeris	+37052685427
Fakso numeris	+37052496084
el. pašto adresas	info@tradintek.com

Šiuo pasiūlymu pažymime, kad sutinkame su visomis pirkimo sąlygomis, nustatytomis:

- 1) atviro konkurso skelbime, paskelbtame Viešųjų pirkimų įstatymo nustatyta tvarka;
- 2) kituose pirkimo dokumentuose (jų paaiškinimuose, papildymuose).

Pasirašydamas CVP IS priemonėmis pateiktą pasiūlymą saugiu elektroniniu parašu, patvirtinu, kad dokumentų skaitmeninės kopijos ir elektroninėmis priemonėmis pateikti duomenys yra tikri.

2 lentelė

SUBTIEKĖJO REKVIZITAI

Eil. Nr.	Subtiekėjo (-ų) pavadinimas (-ai), adresas (-ai)

*Pastaba: pildoma, jei tiekėjas ketina pasitelkti subtiekėją (-us)

3 lentelė

PASIŪLYMO KAINA

Kainų pasiūlymą užpildyti pirkimo dokumentų 6 priede „Kainų pasiūlymo lentelė“ (dokumentas turi būti pateikiamas redaguojamu formatu)

PATEIKIAMŲ DOKUMENTŲ SĄRAŠAS

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius	Failo, kuriame yra dokumentas, pavadinimas
1.	EBVPD	14 psl.	EBVPD
2.	CE sertifikatas Karl Storz	69 psl.	CE sertifikatas_KS
3.	CE sertifikatas LG	2 psl.	CE sertifikatas_LG
4.	8 priedas Tiekėjo deklaracija	1 psl.	8 priedas Tiekėjo deklaracija
5.	7 priedas Deklaracija dėl tiekėjo atsakingų asmenų	1 psl.	7 priedas Deklaracija dėl tiekėjo atsakingų asmenų
6.	Igaliojimas	1 psl.	DK 2024
7.	KAINŲ PASIŪLYMO LENTELE		6 priedas KAINŲ PASIŪLYMO LENTELE
8.	4 priedas Techninė specifikacija	5 psl.	4 priedas TECHNINE SPECIFIKACIJA
9.	Techniniai aprasai	38 psl.	Techniniai aprasai

Pastaba. Perkančioji organizacija atmes tiekėjo pasiūlymą, kaip neatitinkantį pirkimo dokumentuose nustatytų reikalavimų, jeigu kartu su pasiūlymu nebus pateikti pirkimo sąlygų 5.11.2, 5.11.9, 5.11.10 punktuose nurodyti dokumentai.

Pasiūlymas galioja iki termino, nustatyto pirkimo dokumentuose.

Primintina, kad pasiūlyme nurodytos kainos bei įkainiai, taip pat nuolaidos dydis ar įkainio bazė, tiekėjo siūlomų prekių gamintojai, pavadinimai, modeliai, tiekėjo siūlomų prekių techninės specifikacijos, nurodomos užpildant perkančiosios organizacijos pateiktas lenteles, gaminio naudotojo instrukcija, tiekėjo siūlomų prekių atitiktį techninės specifikacijos reikalavimams įrodantys dokumentai - brošiūros, aprašymai, instrukcijos - nėra konfidenciali informacija (plačiau skaityti¹).

Pasiūlymo konfidencialią informaciją sudaro: (tiekėjai turi nurodyti, kokia pasiūlyme pateikta informacija yra konfidenciali. Jei pasiūlyme nėra konfidencialios informacijos, tiekėjas turi nurodyti, kad konfidencialios informacijos pasiūlyme nėra.): konfidencialios informacijos pasiūlyme nėra.

(Tiekėjo arba jo įgalioto asmens
pareigų pavadinimas)

(Parašas)

Vardas, pavardė

¹ https://vpt.lrv.lt/uploads/vpt/documents/files/mp/konfidenciali_informacija.pdf

Tiekėjo pavadinimas (nurodyti): UAB Tradintek

[illegible]

Urologinės endoskopinės įrangos techninė specifikacija (1 kompl.)

Eil. Nr.	Parametrai (specifikacija)	Reikalaujami parametrai ir reikalaujamos parametrų reikšmės	Siūlomi parametrai ir siūlomos parametrų reikšmės
1.	Vaizdo monitorius (kiekis 1 vnt.)		LG 27HK510S, Karl Storz UG520
1.1.	Reikalavimai monitoriui	1. Skystųjų kristalų (LCD tipo arba lygiavertis) monitorius; 2. Įstrižainė ≥ 27 colių; 3. Skiriamoji geba $\geq 1920 \times 1080$ taškų; 4. Vaizdo formatas 16:9; 5. Šviesumas ≥ 450 cd/m ² ; 6. Skirtas naudoti medicinoje; 7. LED tipo arba lygiavertis; 8. Vaizdo perteikimas dviem kanalais: 8.1. Vaizdas vaizde (PIP); 8.2. Vaizdas ne vaizde (POP arba PBP); 9. Svoris ≤ 14 kg.	1. Skystųjų kristalų (IPS tipo) monitorius; 2. Įstrižainė 27 colių; 3. Skiriamoji geba 1920×1080 taškų; 4. Vaizdo formatas 16:9; 5. Šviesumas 1000 cd/m ² ; 6. Skirtas naudoti medicinoje; 7. LED tipo; 8. Vaizdo perteikimas dviem kanalais: 8.1. Vaizdas vaizde (PIP); 8.2. Vaizdas ne vaizde (PBP); 9. Svoris 7,7 kg. Techniniai aprasai psl. 1-4
1.2.	Signalų įvestys	1. 3G-SDI arba 12G-SDI; 2. DVI-D.	1. 3G-SDI; 2. DVI-D. Techniniai aprasai psl. 2
1.3.	Signalų išvestys	Galimybė iš monitoriaus vaizdo signalą perduoti į papildomą monitorių	Galimybė iš monitoriaus vaizdo signalą perduoti į papildomą monitorių Techniniai aprasai psl. 2
1.4.	Komplektacija	Į komplektaciją įeina reguliuojamo aukščio, pasukamas ir palenkiamas/paverčiamas vaizdo monitoriaus laikiklis tvirtinamas prie mobilaus vežimėlio – 1 vnt.	Į komplektaciją įeina reguliuojamo aukščio, pasukamas ir palenkiamas/paverčiamas vaizdo monitoriaus laikiklis tvirtinamas prie mobilaus vežimėlio – 1 vnt. Techniniai aprasai psl. 5
2.	Vaizdo procesorius (kiekis 1 vnt.)		Karl Storz TC100, 20161201

2.1.	Reikalavimai vaizdo procesoriui	<ol style="list-style-type: none"> 1. Ne prastesnis negu „Full HD“ aukštos raiškos standartas; 2. Su integruotu arba atskiru LED tipo (arba lygiaverčiu) šviesos šaltiniu; 3. Baltos šviesos režimas; 4. Automatinis arba rankinis apšvietimo intensyvumo reguliavimas; 5. Valdymas lietimui jautriu ekranu arba kameros galvos mygtukais; 6. Valdymo meniu lietuvių arba anglų kalba; 7. Galimybė didinti endoskopinį vaizdą; 8. Režimas padidinantis spalvų kontrastą audinių diferenciacijai pagerinti arba vaizdo apvertimo ir vaizdo sustabdymo funkcijos; 9. Ne mažiau 3 spalvų arba šviesumo režimo pasirinkimai; 10. Galimybė suvesti paciento duomenis; 11. Nuotraukų formatas JPEG (arba lygiavertis). 	<ol style="list-style-type: none"> 1. „Full HD“ aukštos raiškos standartas; 2. Su atskiru LED tipo šviesos šaltiniu; 3. Baltos šviesos režimas; 4. Rankinis apšvietimo intensyvumo reguliavimas; 5. Valdymas kameros galvos mygtukais; 6. Valdymo meniu anglų kalba; 7. Galimybė didinti endoskopinį vaizdą; 8. Vaizdo apvertimo ir vaizdo sustabdymo funkcijos; 9. Šviesumo režimo pasirinkimai; 10. Galimybė suvesti paciento duomenis; 11. Nuotraukų formatas JPEG. <p>Techniniai aprasai psl. 6-11</p>
2.2.	Signalų išvestys	<ol style="list-style-type: none"> 1. $\geq 1 \times$ HD-SDI arba HD, arba 3G-SDI, arba DVI, arba HDMI; 2. $\geq 1 \times$ DVI arba HDMI. 	<ol style="list-style-type: none"> 1. $1 \times$ DVI; 2. $1 \times$ DVI. <p>Techniniai aprasai psl. 12</p>
3.	Kameros galva (kiekis 1 vnt.)		Karl Storz TH110
3.1.	Reikalavimai kameros galvai	<ol style="list-style-type: none"> 1. Ne prastesnis negu „Full HD“ aukštos raiškos standartas; 2. CMOS jutiklis; 3. Skaitmeninis ar mechaninis priartinimas (vaizdo fokusavimo žiedas arba svirtis); 4. Svoris ≤ 220 g; 5. Židinio nuotolis (angl. focal length) $\geq 1,4$ mm. 	<ol style="list-style-type: none"> 1. „Full HD“ aukštos raiškos standartas; 2. CMOS jutiklis; 3. Skaitmeninis priartinimas (vaizdo fokusavimo žiedas); 4. Svoris 130 g; 5. Židinio nuotolis (angl. focal length) 16 mm. <p>Techniniai aprasai psl. 36-38</p>
4.	Kameros galvos laikiklis (kiekis 1 vnt.)		Karl Storz UG612
4.1.	Reikalavimai kameros galvos laikikliui	<ol style="list-style-type: none"> 1. Turi būti suderinamas su siūloma kameros galva; 2. Turi tvirtintis prie siūlomo mobilaus vežimėlio. 	<ol style="list-style-type: none"> 1. Suderinamas su siūloma kameros galva. 2. Tvirtinasi prie siūlomo mobilaus vežimėlio. <p>Techniniai aprasai psl. 14</p>
5.	Elektrochirurginis generatorius (kiekis 1 vnt.)		Karl Storz UH400, UF902, 27806US

5.1.	Reikalavimai elektrochirurginiam generatoriui	<ol style="list-style-type: none"> 1. Skirtas endoskopinėms, laparoskopinėms ir atviroms operacijoms; 2. Lietimui jautrus valdymo ekranas; 3. Monopoliniai, bipoliniai ir darbo druskos tirpale režimai. Viso ne mažiau 16 darbinių režimų: <ol style="list-style-type: none"> 3.1. ≥ 4 monopoliniai pjovimo režimai; 3.2. ≥ 4 monopolinės koaguliacijos režimai; 3.3. ≥ 6 bipolinės koaguliacijos režimai; 3.4. ≥ 2 pulsuojančios monopoliniai režimai darbui su endoskopu; 4. Instaliuota galios savireguliacijos funkcija (priklausomai nuo pjaunamo audinio varžos); 5. Galimybė išsaugoti prietaiso atmintyje ne mažiau kaip 30 procedūrų; 6. Pasyvaus paciento elektrodo kontakto kontrolės sistema; 7. Galimybė prijungti ≥ 2 monopolinius instrumentus vienu metu; 8. Galimybė prijungti du valdymo pedalus vienu metu arba naudojamas vienas kojinis jungiklis su ≥ 2 pedalais; 9. Saugumo klasė ne žemesnė nei CF. 	<ol style="list-style-type: none"> 1. Skirtas endoskopinėms, laparoskopinėms ir atviroms operacijoms; 2. Lietimui jautrus valdymo ekranas; 3. Monopoliniai, bipoliniai ir darbo druskos tirpale režimai. Viso 43 darbinių režimų: <ol style="list-style-type: none"> 3.1. 14 monopolinių pjovimo režimų; 3.2. 14 monopolinės koaguliacijos režimai; 3.3. 9 bipolinės koaguliacijos režimai; 3.4. 6 pulsuojančios monopoliniai režimai darbui su endoskopu; 4. Instaliuota galios savireguliacijos funkcija (priklausomai nuo pjaunamo audinio varžos); 5. Galimybė išsaugoti prietaiso atmintyje 300 procedūrų; 6. Pasyvaus paciento elektrodo kontakto kontrolės sistema; 7. Galimybė prijungti 2 monopolinius instrumentus vienu metu; 8. Galimybė prijungti du valdymo pedalus vienu metu; 9. Saugumo klasė CF. <p>Techniniai aprasai psl. 15-34</p>
5.2.	Komplektacija	<ol style="list-style-type: none"> 1. Kojinis jungiklis dviejų pedalų – 1 vnt.; 2. Paciento pasyvaus elektrodo laidas – 1 vnt. 	<ol style="list-style-type: none"> 1. Kojinis jungiklis dviejų pedalų – 1 vnt.; 2. Paciento pasyvaus elektrodo laidas – 1 vnt. <p>Techniniai aprasai psl. 35</p>
6.	Mobilus vežimėlis (kiekis 1 vnt.)		Karl Storz UG110
6.1.	Reikalavimai vežimėliui	<ol style="list-style-type: none"> 1. Ratukai 4 vnt., ne mažiau kaip du iš jų fiksuojami ir antistatiniai; 2. Ne mažiau kaip 2 vnt. lentynų; 3. ≥ 1 kanalas įrangos laidams paslėpti. 	<ol style="list-style-type: none"> 1. Ratukai 4 vnt., keturi iš jų fiksuojami ir antistatiniai; 2. 2 vnt. lentynų; 3. 1 kanalas įrangos laidams paslėpti. <p>Techniniai aprasai psl. 13</p>
7.	Žymėjimas CE ženklui	Būtinai (kartu su pasiūlymu privaloma pateikti žymėjimą CE ženklu liudijančio galiojančio dokumento (CE sertifikato arba EB atitikties deklaracijos) kopiją)	Yra, pateiktas.

8.	Įrangos pristatymas ir instaliavimas	Įrangos pristatymo, iškrovimo, pervežimo į instaliavimo vietą, instaliavimo, po instaliavimo likusių įpakavimo medžiagų išvežimo (utilizavimo) išlaidos įskaičiuotos į pasiūlymo kainą.	Įrangos pristatymo, iškrovimo, pervežimo į instaliavimo vietą, instaliavimo, po instaliavimo likusių įpakavimo medžiagų išvežimo (utilizavimo) išlaidos įskaičiuotos į pasiūlymo kainą.
9.	Vartotojų apmokymas	Vartotojų apmokymas naudoti įrangą įskaičiuotas į pasiūlymo kainą.	Vartotojų apmokymas naudoti įrangą įskaičiuotas į pasiūlymo kainą.
10.	Techninio personalo apmokymas	LSMU ligoninės Kauno klinikų Medicininės technikos tarnybos inžinierių apmokymas atlikti įrangos pogarantinę techninę priežiūrą įskaičiuotas į pasiūlymo kainą.	LSMU ligoninės Kauno klinikų Medicininės technikos tarnybos inžinierių apmokymas atlikti įrangos pogarantinę techninę priežiūrą įskaičiuotas į pasiūlymo kainą.
11.	Garantinis laikotarpis	≥ 36 mėnesiai	36 mėnesiai
12.	Kartu su įranga pateikiama dokumentacija	<ol style="list-style-type: none"> 1. Naudojimo instrukcija lietuvių ir anglų kalba; 2. Serviso dokumentacija lietuvių arba anglų kalba: <ol style="list-style-type: none"> a) Struktūrinė schema ir/arba atskirų blokų funkcijų aprašymas; b) Instaliavimo instrukcijos; c) Funkcionalumo patikrinimo instrukcijos; d) Aptarnavimo instrukcijos; e) Gedimų nustatymo instrukcijos; f) Išardymo-surinkimo instrukcijos; g) Atsarginių dalių katalogas; h) Periodinio techninės būklės tikrinimo instrukcijos; i) Derinimo/kalibravimo instrukcijos (<i>taikoma, jei šios procedūros yra numatytos siūlomos įrangos gamintojo</i>); j) Programinė įranga, serviso slaptažodžiai bei aparatūriniai „raktai“ b), c), d), e), h) ir i) punktuose nurodytiems darbams atlikti (<i>taikoma, jei šios priemonės yra numatytos siūlomos įrangos gamintojo</i>). 	<ol style="list-style-type: none"> 1. Naudojimo instrukcija lietuvių ir anglų kalba; 2. Serviso dokumentacija lietuvių arba anglų kalba: <ol style="list-style-type: none"> a) Struktūrinė schema ir/arba atskirų blokų funkcijų aprašymas; b) Instaliavimo instrukcijos; c) Funkcionalumo patikrinimo instrukcijos; d) Aptarnavimo instrukcijos; e) Gedimų nustatymo instrukcijos; f) Išardymo-surinkimo instrukcijos; g) Atsarginių dalių katalogas; h) Periodinio techninės būklės tikrinimo instrukcijos; i) Derinimo/kalibravimo instrukcijos (<i>taikoma, jei šios procedūros yra numatytos siūlomos įrangos gamintojo</i>); <p>Programinė įranga, serviso slaptažodžiai bei aparatūriniai „raktai“ b), c), d), e), h) ir i) punktuose nurodytiems darbams atlikti (<i>taikoma, jei šios priemonės yra numatytos siūlomos įrangos gamintojo</i>).</p>
13.	Galimybė įsigyti originalias (arba	Tiekėjas turi užtikrinti galimybę įsigyti siūlomos prekės originalias (arba joms lygiavertes) atsargines	Tiekėjas užtikrina galimybę įsigyti siūlomos prekės

	<p>joms lygiavertės) atsarginės dalis</p>	<p>dalys (jų tiekimą rinkai) ne trumpiau kaip 5 metus (<i>prašome nurodyti konkrečią trukmę</i>) nuo prekės garantinio laikotarpio pabaigos, išskyrus atvejus, kai siūlomos prekės originalios (arba joms lygiavertės) atsarginės dalys dėl objektyvių priežasčių negali būti tiekiamos Lietuvos Respublikos rinkai (<i>būtinai tiekėjo ir/arba gamintojo atitinkamas patvirtinimas</i>).</p> <p><u>Pastaba:</u> Reikalavimas taikomas vadovaujantis Lietuvos Respublikos aplinkos ministro 2022 m. gruodžio 13 d. įsakymu Nr. D1-401 patvirtinto aplinkos apsaugos kriterijų taikymo, vykdant žaliuosius pirkimus, tvarkos aprašo II skyriaus 4.4.4.4 punktu.</p>	<p>originalias (arba joms lygiavertės) atsarginės dalis (jų tiekimą rinkai) 5 metus nuo prekės garantinio laikotarpio pabaigos, išskyrus atvejus, kai siūlomos prekės originalios (arba joms lygiavertės) atsarginės dalys dėl objektyvių priežasčių negali būti tiekiamos Lietuvos Respublikos rinkai (<i>būtinai tiekėjo ir/arba gamintojo atitinkamas patvirtinimas</i>).</p> <p><u>Pastaba:</u> Reikalavimas taikomas vadovaujantis Lietuvos Respublikos aplinkos ministro 2022 m. gruodžio 13 d. įsakymu Nr. D1-401 patvirtinto aplinkos apsaugos kriterijų taikymo, vykdant žaliuosius pirkimus, tvarkos aprašo II skyriaus 4.4.4.4 punktu.</p>
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Europos bendrasis viešųjų pirkimų dokumentas (EBVPD)

I dalis. Informacija apie pirkimo procedūrą ir perkančiąją organizaciją ar perkantįjį subjektą

Informacija apie paskelbimą

Skelbimo numeris OL S (tik tarptautiniams pirkimams):

-

Skelbimo numeris CVP IS (kur rasti?)

-

Perkančiosios organizacijos / Perkančiojo subjekto tapatybė

Oficialus pavadinimas:

LSMUL KAUNO KLINIKOS

Šalis:

Lietuva

Informacija apie pirkimo procedūrą

Procedūros tipas

Atvira

Pavadinimas:

UROLOGINĖ ENDOSKOPINĖ ĮRANGA

Trumpas aprašymas:

UROLOGINĖ ENDOSKOPINĖ ĮRANGA

Perkančiosios organizacijos ar perkančiojo subjekto (jei taikoma) priskirtas dokumento numeris:

-

II dalis. Informacija apie ekonominės veiklos vykdytoją

A. Informacija apie ekonominės veiklos vykdytoją

Tiekėjo pavadinimas arba vardas ir pavardė (jei fizinis asmuo):

UAB Tradintek

Gatvė ir namo numeris:

J. Jasinskio g. 9

Pašto kodas:

01112

Miestas:

Vilnius

Šalis:

Lietuva

Interneto adresas (jei yra):

-

E. paštas:

[redacted]

Telefonas:

[redacted]

Asmuo ar asmenys ryšiams:

[redacted]

PVM mokėtojo kodas, jei yra:

LT249421811

Jei PVM mokėtojo kodo nėra, nurodykite kitą nacionalinį identifikacinį numerį (Lietuvoje - įmonės kodą)

-

Ar ekonominės veiklos vykdytojas yra labai maža, mažoji ar vidutinė įmonė?

☒ Taip

☐ Ne

Tik tuo atveju, kai pirkimas rezervuotas: ar ekonominės veiklos vykdytojas yra globojama darbo grupė (neįgalųjų socialinė įmonė), socialinė įmonė? Ar jis vykdys sutartį pagal globojamų darbo grupių (neįgalųjų socialinių įmonių) užimtumo programas?

☐ Taip

☒ Ne

Jei taikoma, ar ekonominės veiklos vykdytojas įtrauktas į oficialų patvirtintų ekonominės veiklos vykdytojų sąrašą arba ar jis turi lygiavertį sertifikatą (pvz., pagal nacionalinę (išankstinę) kvalifikacijos vertinimo sistemą)? Lietuvos tiekėjai renkasi „ne“

☐ Taip

☒ Ne

- Be to, užpildykite trūkstamą informaciją IV dalies A, B, C arba D skirsniuose, atsižvelgdami į konkretų atvejį TIK jei to reikalaujama atitinkamame skelbime arba pirkimo dokumentuose:

e) Ar ekonominės veiklos vykdytojas galės pateikti sertifikatą dėl socialinio draudimo įmokų ir mokesčių mokėjimo arba pateikti informaciją, kuri leistų perkančiajai organizacijai ar perkančiajam subjektui jį gauti tiesiogiai naudojantis prieiga prie bet kurios iš valstybių narių nemokamos nacionalinės duomenų bazės?

☒ Taip

☐ Ne

Jei atitinkami dokumentai prieinami elektroniniu būdu, nurodykite:

<http://www.sodra.lt>

Ar ekonominės veiklos vykdytojas pirkimo procedūroje dalyvauja kartu su kitais? Žymima TAIP, jei pasiūlymą teikia ūkio subjektų grupė (konsorciumas) pagal jungtinės veiklos sutartį

☐ Taip

☒ Ne

Jei pirkimas padalintas į dalis, nuoroda į pirkimo dalį (-is), dėl kurios (-ių) ekonominės veiklos vykdytojas nori dalyvauti konkurse:

-

B. Informacija apie ekonominės veiklos vykdytojo teisinius atstovus #1

- Šis skirsnis pildomas, jeigu tiekėjo vadovas įgalioja kitą asmenį pasirašyti pasiūlymą, bendrauti su pirkimo vykdytoju, įgalioja atstovauti ir pasirašyti EBVPD, bendrauti su pirkimo vykdytoju dėl EBVPD pateiktos informacijos, teikiamų kvalifikaciją ir pašalinimo pagrindų nebuvimą pagrindžiančių dokumentų, dėl pasiūlymo ir pan.

Jei taikytina, nurodykite asmens (-ų), įgalioto (-ų) atstovauti ekonominės veiklos vykdytojui šios pirkimo procedūros tikslais, vardą ir pavardę ir adresą:

Vardas

Pavardė

Gimimo data

-

Gimimo vieta

-

Gatvė ir namo numeris:

-

Pašto kodas:

-

Miestas:

-

Šalis:

Lietuva

E. paštas:

Telefonas:

Pareigos arba statusas:

-

Prireikus pateikite išsamią informaciją apie atstovavimą (formą, aprėptį, paskirtį ir t. t.):

-

C. Informacija apie rėmimąsi kitų subjektų pajėgumais

Ar siekdamas patenkinti IV dalyje nurodytus atrankos kriterijus ir V dalyje nurodytus kriterijus bei taisykles (jei tokių yra) ekonominės veiklos vykdytojas remiasi kitų subjektų pajėgumais?

☐ Taip

☒ Ne

D. Informacija apie subrangovus, kurių pajėgumais ekonominės veiklos vykdytojas nesiremia

- (Skirsnį reikia pildyti, tik jei šios informacijos aiškiai reikalauja perkančioji organizacija ar perkantysis subjektas.)

Ar ekonominės veiklos vykdytojas ketina kurias nors sutarties dalis subrangos sutartimi pavesti atlikti trečiosioms šalims?

☐ Taip

☒ Ne

- Jei perkančioji organizacija ar perkantysis subjektas aiškiai prašo šios informacijos, šalia informacijos pagal šį skirsnį, pateikite pagal šios dalies A ir B skirsnius ir III dalį reikalaujamą informaciją apie kiekvieną susijusį subrangovą (subrangovų kategorijas).

III dalis. Pašalinimo pagrindai

A. Su baudžiamaisiais nuosprendžiais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 1 dalyje nustatyti šie pašalinimo pagrindai

A1. Dalyvavimas nusikalstamos organizacijos veikloje (VPĮ 46 str. 1 d. 1 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už dalyvavimą nusikalstamos organizacijos veikloje, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2008 m. spalio 24 d. Tarybos pamatinio sprendimo 2008/841/TVR dėl kovos su organizuotu nusikalstamumu 2 straipsnyje (OL L 300, 2008 11 11, p. 42).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A2. Korupcija (VPĮ 46 str. 1 d. 2 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už korupciją, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo

laikotarpis tebesitęsia? Kaip apibrėžta Konvencijos dėl kovos su korupcija, susijusia su Europos Bendrijų pareigūnais ar Europos Sąjungos valstybių narių pareigūnais, 3 straipsnyje (OL C 195, 1997 6 25, p. 1) ir 2003 m. liepos 22 d. Tarybos pamatinio sprendimo 2003/568/TVR dėl kovos su korupcija privačiame sektoriuje 2 straipsnio 1 dalyje (OL L 192, 2003 7 31, p. 54). Į pašalinimo pagrindus taip pat įtraukta korupcija, kaip apibrėžta perkančiosios organizacijos (perkančiojo subjekto) arba ekonominės veiklos vykdytojo nacionalinėje teisėje.

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A3. Sukčiavimas (VPĮ 46 str. 1 d. 3 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už sukčiavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Pagal Europos Bendrijų finansinių interesų apsaugos konvencijos 1 straipsnį (OL C 316, 1995 11 27, p. 48).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A4. Teroristiniai nusikaltimai arba su teroristine veikla susiję nusikaltimai (VPĮ 46 str. 1 d. 5 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už teroristinius nusikaltimus arba

su teroristine veikla susijusius nusikaltimus, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2002 m. birželio 13 d. Tarybos pamatinio sprendimo dėl kovos su terorizmu 1 ir 3 straipsniuose (OL L 164, 2002 6 22, p. 3). Į pašalinimo pagrindus taip pat įtrauktas nusikalstamos veikos kurstymas, pagalba ar bendrininkavimas ją vykdant arba kėsینimasis ją įvykdyti, kaip nurodyta to pamatinio sprendimo 4 straipsnyje.

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A5. Pinigų plovimas arba teroristų finansavimas (VPĮ 46 str. 1 d. 6 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už pinigų plovimą arba teroristų finansavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2005 m. spalio 26 d. Europos Parlamento ir Tarybos direktyvos 2005/60/EB dėl finansų sistemos apsaugos nuo jos panaudojimo pinigų plovimui ir teroristų finansavimui 1 straipsnyje (OL L 309, 2005 11 25, p. 15).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A6. Vaikų darbas ir kitos prekybos žmonėmis formos (VPĮ 46 str. 1 d. 7 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo,

sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už vaikų darbą arba kitas prekybos žmonėmis formas, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2011 m. balandžio 5 d. Europos Parlamento ir Tarybos direktyvos 2011/36/ES dėl prekybos žmonėmis prevencijos, kovos su ja ir aukų apsaugos, pakeičiančios Tarybos pamatinį sprendimą 2002/629/TVR, 2 straipsnyje (OL L 101, 2011 4 15, p. 1).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

B. Su mokesčių ar socialinio draudimo įmokų mokėjimu susiję pagrindai **Direktyvos 2014/24/ES 57 straipsnio 2 dalyje nustatytos šios pašalinimo priežastys**

B1. Mokesčių mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su mokesčių mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

B2. Socialinio draudimo įmokų mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su socialinio draudimo įmokų mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☒ Taip

☐ Ne

URL

http://draudejai.sodra.lt/draudeju_viesi_duomenys/

Kodas

191630223

Emitentas

Valstybinio socialinio draudimo fondo valdyba prie Socialinės apsaugos ir darbo ministerijos

C. Su nemokumu, interesų konfliktu ar profesiniais nusižengimais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 4 dalyje nustatyti šie pašalinimo pagrindai

C10. Su kitais ekonominės veiklos vykdytojais sudaryti susitarimai, kuriais siekta iškreipti konkurenciją (VPĮ 46 str. 4 d. 1 p.)

Ar ekonominės veiklos vykdytojas su kitais ekonominės veiklos vykdytojais yra sudaręs susitarimų, kuriais siekta iškreipti konkurenciją atliekamame pirkime?

Jūsų atsakymas

☐ Taip

☒ Ne

C11. Rimti profesiniai pažeidimai VPĮ 46 str. 4 d. 7 p., VPĮ 46 str. 6 d. 3 p.

Pirkimams pradėtiems nuo 2022-01-01: Ar ekonominės veiklos vykdytojas yra padaręs rimtą profesinį pažeidimą, kaip nurodyta žemiau?:

a) yra padaręs finansinės atskaitomybės ir audito teisės aktų pažeidimą ir nuo jo padarymo dienos praėjo mažiau kaip vieni metai; **Nuo 2022-08-12**

pildydamas EBVPD tiekėjas yra informuotas ir supranta, kad finansinės atskaitomybės ir audito teisės aktų pažeidimu taip pat gali būti laikomi atvejai, kai tiekėjas nepateikia privalomų finansinės atskaitomybės dokumentų Registrų centrui. Išsamiau: <https://vpt.lrv.lt/lt/naujienos/>

finansiniu-ataskaitu-nepateikimas-gali-tapti-kliutimi-dalyvauti-viesuosiuose-pirkimuose

b) neatitinka minimalių patikimo mokesčių mokėtojo kriterijų, nustatytų Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje. Taikant šį tiekėjo pašalinimo iš pirkimo procedūros pagrindą, vadovaujamosi Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje nustatytais terminais, juos skaičiuojant nuo Mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje nurodytų pažeidimų padarymo dienos, tačiau visais atvejais šie terminai negali būti ilgesni negu 3 metai;

c) yra padaręs draudimo sudaryti draudžiamus susitarimus, įtvirtinto Lietuvos Respublikos konkurencijos įstatyme ar panašaus pobūdžio kitos valstybės teisės akte, pažeidimą ir nuo jo padarymo dienos praėjo mažiau kaip 3 metai;

d) yra padaręs bet kokią kitą rimtą profesinį pažeidimą, nenurodytą aukščiau, nuo kurio padarymo dienos praėjo mažiau kaip vieni metai?

Pirkimams pradėti iki 2022-01-01: Ar ekonominės veiklos vykdytojas yra pripažintas kaltu dėl sunkaus profesinio nusižengimo kaip nurodyta žemiau?

I. ar ekonominės veiklos vykdytojas yra padaręs profesinį pažeidimą, kai už finansinės atskaitomybės ir audito teisės aktų pažeidimus ekonominės veiklos vykdytojui ar jo vadovui paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos įstatymuose ar kitų valstybių teisės aktuose, ir nuo sprendimo, kuriuo buvo paskirta ši sankcija, įsiteisėjimo dienos arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, praėjo mažiau kaip vieni metai?

II. Ar ekonominės veiklos vykdytojas yra padaręs kurį nors vieną iš žemiau nurodytų rimtų profesinių pažeidimų(taikoma tik tada kai, ir tik tiek, kiek apibrėžta kituose pirkimo dokumentuose):

a) profesinės etikos pažeidimas, kai nuo ekonominės veiklos vykdytojo pripažinimo nesilaikančiu profesinės etikos normų momento praėjo mažiau kaip vieni metai;

b) konkurencijos, darbuotojų saugos ir sveikatos, informacijos apsaugos, intelektinės nuosavybės apsaugos pažeidimas, už kurį ekonominės veiklos vykdytojui ar jo vadovui yra paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos ar kitų valstybių įstatymuose, kai nuo sprendimo, kuriuo buvo paskirta ši sankcija, arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, įsiteisėjimo dienos praėjo mažiau kaip vieni metai;

c) draudimo sudaryti draudžiamus susitarimus, įtvirtinto Lietuvos Respublikos konkurencijos įstatyme ar panašaus pobūdžio kitos valstybės teisės akte, pažeidimas, kai nuo sprendimo paskirti Konkurencijos įstatyme ar kitos valstybės teisės akte nustatytą ekonominę sankciją įsiteisėjimo dienos praėjo mažiau kaip 3 metai;

d) ekonominės veiklos vykdytojas, kuris yra fizinis asmuo, arba ekonominės veiklos vykdytojo, kuris yra juridinis asmuo, kita organizacija ar jos padalinys, vadovas, kitas valdymo ar priežiūros organo narys ar kitas asmuo, turintis (turintys) teisę atstovauti ekonominės veiklos vykdytojui ar jį kontroliuoti, jo vardu priimti sprendimą, sudaryti sandorį, arba dalyvis, turintis balsų daugumą juridinio asmens dalyvių susirinkime, yra pripažintas kaltu dėl tyčinio bankroto, kaip jis apibrėžtas Lietuvos Respublikos įmonių bankroto įstatyme ar panašaus pobūdžio kitų valstybių teisės aktuose, kai nuo teismo sprendimo įsiteisėjimo dienos praėjo mažiau kaip 3 metai?

Jūsų atsakymas

☐ Taip

☒ Ne

C12. Interesų konfliktas dėl dalyvavimo pirkimo procedūroje (VPĮ 46 str. 4 d. 2 p.)

Ar ekonominės veiklos vykdytojas žino apie kokius nors [interesų konfliktus](#), kaip nurodyta nacionalinėje teisėje, atitinkamame skelbime ar pirkimo dokumentuose, kylančius dėl jo dalyvavimo pirkimo procedūroje?

Jūsų atsakymas

☐ Taip

☒ Ne

C13. Tiesioginis arba netiesioginis dalyvavimas rengiant šią pirkimo procedūrą (46 str. 4 d. 3 p.)

Ar ekonominės veiklos vykdytojas arba su juo susijusi įmonė konsultavo perkančiąją organizaciją ar perkantįjį subjektą arba kitaip dalyvavo rengiant pirkimo procedūrą?

Jūsų atsakymas

☒ Taip

☐ Ne

Pateikite išsamią informaciją apie tai

Perkančiajai organizacijai teiktas komercinis pasiūlymas pirkimo objektui.

C14. Sutarties nutraukimas anksčiau laiko, žala ar kitos panašios sankcijos (VPĮ 46 str. 4 d. 6 p.)

Ar ekonominės veiklos vykdytojas turėjo tokios patirties: ankstesnė viešoji sutartis, ankstesnė sutartis su perkančiuoju subjektu arba ankstesnė koncesijos sutartis buvo nutraukta anksčiau laiko; arba buvo pareikalauta atlyginti su ankstesne sutartimi susijusią žalą ar skirtos kitos panašios sankcijos?

Lietuvoje (be kita ko) - ar ekonominės veiklos vykdytojas yra įtrauktas į nepatikimų tiekėjų sąrašą ?

Jūsų atsakymas

☐ Taip

☒ Ne

C15. Pripažinimas kaltu dėl faktų iškraipymo, informacijos nuslėpimo, negalėjimas pateikti reikalaujamų dokumentų ir su šia procedūra susijusios konfidencialios informacijos gavimas (46 str. 4 d. 4 p. ir 46 str. 4 d. 5 p.)

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai jis :

a) buvo labai iškreipęs faktus pateikdamas informaciją (**pateikęs melagingą informaciją**), reikalingą patikrinti, ar nėra pagrindų pašalinti, arba patikrinti atitiktį atrankos kriterijams;

b) slėpė tokią informaciją;

c) delsė pateikti patvirtinamuosius dokumentus, kurių reikalavo perkančioji organizacija ar perkantysis subjektas,

d) siekė daryti neteisėtą įtaką perkančiosios organizacijos ar perkančiojo subjekto sprendimų priėmimo procesui, kad gautų konfidencialios informacijos, dėl kurios per pirkimo procedūrą įgytų nepagrįstą pranašumą, arba tyčia teikti klaidinančios informacijos, kuri gali turėti esminės įtakos sprendimams dėl pašalinimo, atrankos ar sutarties skyrimo?

Jūsų atsakymas

☐ Taip

☒ Ne

D. Išimtinai nacionaliniai pašalinimo pagrindai

Išimtinai nacionaliniai pašalinimo pagrindai, nurodyti atitinkamame skelbime ar pirkimo dokumentuose.

D1. Išimtinai nacionaliniai pašalinimo pagrindai (VPĮ 46 str. 1 d. 4 p.)

Pirkimams pradėtiems nuo 2022-01-01:

pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo **nuteistas galutiniu teismo sprendimu už nusikalstamą bankrotą**, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia?

Pirkimams pradėtiems iki 2022-01-01:

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai:

a) jis **neatitinka minimalių patikimo mokesčių mokėtojo kriterijų**, nustatytų Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje ir dėl to laikomas padariusiu šiurkštų profesinį pažeidimą.

b) pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo **nuteistas galutiniu teismo sprendimu už nusikalstamą bankrotą**, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

IV dalis. Atrankos kriterijai

α. Visų atrankos kriterijų bendra nuroda

Dėl atrankos kriterijų ekonominės veiklos vykdytojas pareiškia, kad jis atitinka visus reikalaujamus atrankos kriterijus

Jūsų atsakymas

☒ Taip

☐ Ne

Baigti

IV dalis. Baigiamieji pareiškimai

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad II–V dalyse pateikta informacija yra tiksli ir teisinga ir kad ji pateikta visiškai suvokiant didelio faktų iškreipimo padarinius.

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad pareikalavus gali nedelsdami pateikti nurodytus sertifikatus ir kitų formų įrodomuosius dokumentus, išskyrus tuos atvejus, kai:

a) perkančioji organizacija ar perkantysis subjektas turi galimybę atitinkamus patvirtinamuosius dokumentus tiesiogiai gauti naudodamiesi prieiga prie bet

kurios iš valstybių narių nemokamos nacionalinės duomenų bazės (su sąlyga, kad ekonominės veiklos vykdytojas pateikė reikalingą informaciją (interneto adresą, išduodančiąją instituciją ar įstaigą, tiksliai dokumentų nuorodas), kuri perkančiajai organizacijai ar perkančiajam subjektui leidžia tai padaryti (pareikalavus dėl tokios prieigos turi būti pridėtas atitinkamas sutikimas), arba b) perkančioji organizacija ar perkantysis subjektas yra gavusi ir turi aktualius susijusius dokumentus iš ankstesnių (kitų) pirkimo procedūrų.

Ekonominės veiklos vykdytojai oficialiai sutinka perkančiajai organizacijai ar perkančiajam subjektui, nurodytam I dalyje, leisti susipažinti su dokumentais, kuriais patvirtinama informacija, pateikta šio Europos bendrojo viešųjų pirkimų dokumento III ir IV dalyse, kiek tai susiję su pirkimu, nurodytu I dalyje.

Data, vieta ir, jei reikia ar būtina, parašas (-ai):

Data

08-01-2025

Vieta

Vilnius

Parašas

VALSTYBĖS ĮMONĖ REGISTRŲ CENTRAS

Studentų g. 39, 08106 Vilnius, tel. +370 5 268 8262, el. p. info@registrucentras.lt

**KOMPETENTINGŲ INSTITUCIJŲ TVARKOMŲ JUNGTINIŲ DUOMENŲ APIE VIEŠŲJŲ
PIRKIMŲ PROCEDŪROJE DALYVAUJANTĮ TIEKĖJĄ (JURIDINĮ ASMENĮ)
PAŽYMA**

2025-04-16 Nr. 764342

Tiekėjo pavadinimas	Uždaroji akcinė bendrovė "TRADINTEK"
Tiekėjo kontaktinė informacija:	
mobilusis telefonas	
elektroninio pašto adresas	info@tradintek.com
Buhalterio (buhalterių) ar kito (kitų) asmens (asmenų), turinčio (turinčių) teisę surašyti ir pasirašyti tiekėjo apskaitos dokumentus, vardas, pavardė	
<u>Juridinių asmenų registras:</u>	
kodas	124942182
teisinė forma	Uždaroji akcinė bendrovė
teisinis statusas	Teisinis statusas neįregistruotas
buveinė (adresas)	Vilnius, Biržiškų g. 125, LT-11112
Vadovo, kito valdymo ar priežiūros organo nario ar kito asmens, turinčio (turinčių) teisę atstovauti tiekėjui ar jį kontroliuoti, jo vardu priimti sprendimą, sudaryti sandorį, vardas, pavardė	TOMAS MICKŪNAITIS
įregistravimo data	1999-07-15
<u>Valstybinė mokesčių inspekcija prie Lietuvos Respublikos finansų ministerijos:</u>	
duomenys apie tiekėjo atsiskaitymą su valstybės, savivaldybių biudžetais ir valstybės pinigų fondais	Atsiskaitęs
Duomenų suformavimo data	2025-04-15
<u>Valstybinio socialinio draudimo fondo valdyba prie Socialinės apsaugos ir darbo ministerijos:</u>	
duomenys apie tiekėjo atsiskaitymą su Valstybinio socialinio draudimo fondu	Neįsiskolinęs
Duomenų suformavimo data	2025-04-15
<u>Įtariamųjų, kaltinamųjų ir nuteistųjų registras:</u>	
duomenys apie tiekėją	Dėl uždarnosios akcinės bendrovės "TRADINTEK", kodas 124942182, per pastaruosius 5 metus nėra priimtas ir įsiteisėjęs apkaltinamasis teismo nuosprendis už nusikalstamas veikas, nurodytas Lietuvos Respublikos viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje ir 3 dalyje. Nėra paskirta baudžiamojo poveikio priemonė - uždraudimas juridiniam asmeniui dalyvauti viešuosiuose pirkimuose pagal Viešųjų pirkimų įstatymo 46 straipsnio 2-1 dalį.
duomenys apie tiekėjo vadovą, kitą valdymo ar priežiūros organo narį ar kitą (kitus) asmenį (asmenis), turintį (turinčius) teisę atstovauti	Tomui Mickūnaičiui per pastaruosius 5 metus nėra priimtas ir įsiteisėjęs apkaltinamasis teismo nuosprendis ir jis neturi neišnykusio ar nepanaikinto teistumo už

tiekėjui ar jį kontroliuoti, jo vardu priimti
sprendimą, sudaryti sandorį

duomenys apie tiekėjo buhalterį (buhalterius) ar
kitą (kitus) asmenį (asmenis), turintį (turinčius)
teisę surašyti ir pasirašyti tiekėjo apskaitos
dokumentus

Duomenų suformavimo data

**nusikalstamas veikas, nurodytas Lietuvos Respublikos
viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje.**

**[redacted], per
pastaruosius 5 metus nėra priimtas ir įsiteisėjęs
apkaltinamasis teismo nuosprendis ir jis neturi
neišnykusio ar nepanaikinto teistumo už
nusikalstamas veikas, nurodytas Lietuvos Respublikos
viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje.**

2025-04-16

Pažymą išspausdino:

Asmenų registravimo centro Juridinių asmenų registro
Vilniaus skyriaus Vilniaus 2 Juridinių asmenų registro
duomenų tvarkymo grupės
Registratorė

[redacted]

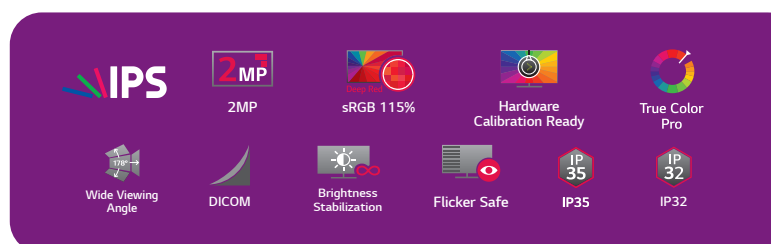
A. V.

DETALŪS METADUOMENYS	
Dokumento sudarytojas (-ai)	Valstybės įmonė Registrų centras
Dokumento pavadinimas (antraštė)	Jungtinė pažyma
Dokumento registracijos data ir numeris	2025-04-16 Nr. SP-74968 (4.55 Mr)
Dokumento gavimo data ir dokumento gavimo registracijos numeris	-
Dokumento adresatas (-ai)	Kiti
Dokumento specifikacijos identifikavimo žymuo	ADOC-V1.0
Parašo paskirtis	Pasirašymas
Parašą sukūrusio asmens vardas, pavardė ir pareigos	
Parašo sukūrimo data ir laikas	2025-04-16 14:23
Parašo formatas	Trumpalaikio galiojimo (XAdES-T)
Laiko žymoje nurodytas laikas	2025-04-16 14:23
Informacija apie sertifikavimo paslaugų teikėją	RCSC IssuingCA-2
Sertifikato galiojimo laikas	2024-10-15 14:07 - 2026-10-15 14:07
Informacija apie būdus, naudotus metaduomenų vientisumui užtikrinti	-
Pagrindinio dokumento priedų skaičius	0
Pagrindinio dokumento pridedamų dokumentų skaičius	0
Programinės įrangos, kuria naudojantis sudarytas elektroninis dokumentas, pavadinimas	Elpako v.20250403.1
Informacija apie elektroninio dokumento ir elektroninio (-ių) parašo (-ų) tikrinimą (tikrinimo data)	Tikrinant dokumentą nenustatyta jokių klaidų (2025-04-16)
Elektroninio dokumento nuorašo atspausdinimo data ir ją atspausdinęs darbuotojas	2025-04-16 nuorašą suformavo Dokumentų valdymo sistema RC E.SD (5)
Paieškos nuoroda	-
Papildomi metaduomenys	-

LG Full HD Surgical Monitor



6. Skirtas naudoti medicinoje;

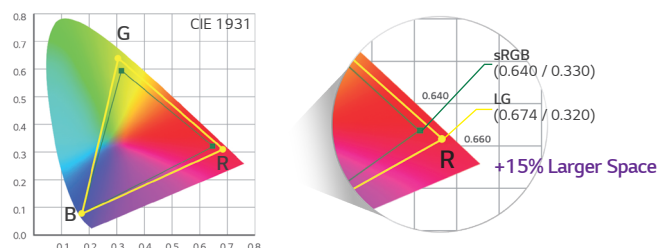


27HK510S

Optimal Image Quality for Fine Surgery

Full HD* IPS Display with sRGB 115%(Deep Red)

The Full HD IPS display with sRGB 115% (Deep Red) is designed to fit with other Full HD surgical devices. It enables surgeons to view accurate, realistic images by maximizing compatibility and clearer, brighter color reproduction, especially in the red color spectrum.



*FHD: 1920x1080

DICOM* Part 14 & Brightness Stabilization

The LG surgical monitor carefully measures and sets every grayscale tone as well to create a monitor compliant with DICOM Part 14 and ensure the most accurate outcome. And, its stabilized brightness settings quickly adapt to the surgical procedure and local lighting conditions.

Brightness Stabilization*

Non Brightness Stabilization
(conventional display)*



*DICOM: Digital Imaging and Communications in Medicine.

Designed for Use in the Operating Room

IP35 & IP32 : Dustproof & Water Resistance

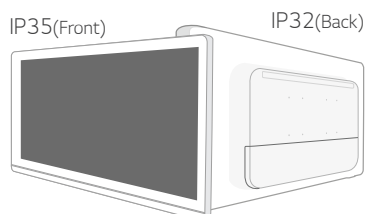
To ensure protection against contact with substances such as blood or bodily fluids, LG surgical monitors are cleanable and durable, with ratings of IP35 on the front and IP32 on the back, securing them from any direction.



Dustproof

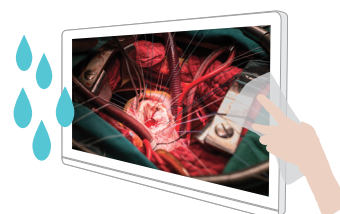


Waterproof



Anti-Reflection & Protection Glass

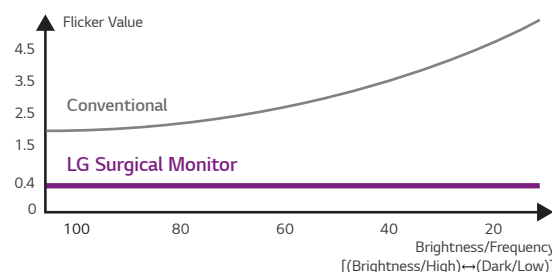
The LG surgical monitor with protection glass provides a more durable display by safeguarding the monitor from water and bodily fluids and making it easier to clean. The improved anti-reflection ability enables a brighter, sharper display for optimal image quality.



Long-lasting Eye Comfort

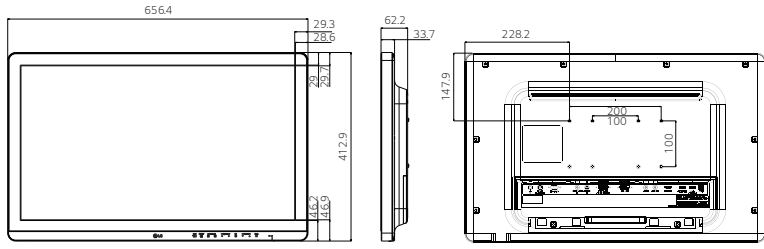

Flicker Safe

Flicker Safe reduces the onscreen flicker level to almost zero, which helps minimize eye strain and eye fatigue. By combining Flicker Safe with the proven picture quality of IPS technology, users can comfortably work throughout the day.



*This result based on internal LGE lab tests.

Specification

Model Name		27HK510S	
External Dimension			
			
Panel	Type	2. Įstrižainė 27 colių;	IPS 1. Skystųjų kristalų (IPS tipo) monitorius;
	Size		27" (16:9)
	Native Resolution	4. Vaizdo formatas 16:9;	1920 x 1080 3. Skiriamoji geba 1920x1080 taškų;
	Pixel Pitch		0.3144 mm x 0.3114 mm
	Display Colors		10bit / sRGB 115% (Deep Red)
	Viewing Angles		178/178
	Brightness	5. Šviesumas 1000 cd/m2;	1000cd/m ² (Typ.)
	Surface Treatment		Protection Glass
	Contrast Ratio		1000:1 (Typ.)
	Response Time		14ms (Typ.)
Video Signals	Input Terminals	1. 3G-SDI; 2. DVI-D.	HDMI (1.4) x 1, S-Video x 1, Composite x 1, 3G-SDI x 1, DVI-I x 1 (Compatible with D-sub & Component via adapter)
	Output Terminals		3G-SDI x 1, DVI-D x 1
	Digital Scanning Frequency (H/V)		HDMI, DVI-D: 30~83kHz / 56~61Hz, D-sub: 30~83kHz / 56~61Hz
	Sync Formats		Dynamic Sync Mode (Thru Mode)
USB	Function		1 upstream, 1 downstream (For Calibration)
	Standard		USB 3.0
Power	Power Requirements		100-240Vac, 50/60Hz
	Maximum Power Consumption		120W
	Power Management		0.3W
Brightness Stabilization		Support	
Resistance Rating		IP35 / IP32 (Front / Back), 8H Glass, IK06	
Gamma		Gamma 1.8 / Gamma 2.0 / Gamma 2.2 Gamma 2.4 / Gamma 2.6 DICOM Gamma curve	
Certifications & Standards		IEC(IEC60601-1 / IEC60601-1-2), FCC(FCC part 15 Class A), CB, ANSI/AAMI ES 60601-1, CSA CAN/CSA-C22.2 NO. 60601-1, RoHS, REACH, WEEE, CE MDD(Class 1)	
Supplied Accessories		Power Cord, DVI-I to D-Sub Adapter, DVI-D cable, HDMI cable, Adapter, CD/book manual	
Physical Specifications	Weight(Without Stand)	7.7kg 9. Svoris 7,7 kg.	

*The monitor stand is not included with the surgical monitor.

https://www.lg.com/uk/business/monitor/medical-display-device/surgical-monitors/27hk510s-w/

All Spec

DISPLAY

Aspect Ratio
16:9

7. LED tipo;

Backlight Technology
LED

Brightness (Typ.)
1000cd/m²

Colour Bit
10bit

Colour Gamut (Typ.)
sRGB 115% (Area),
sRGB over 99% (Coverage)

Contrast Ratio with DFC
Mega

Peak Brightness (Min.)
650cd/m² (Peak)

Pixel Pitch (H x V)
0.3114mm x 0.3114mm

Response Time (GTG)
14ms (Off-setting), 5ms (Faster-setting)

Size (cm)
68.58

Viewing Angle (CR≥10)
178°(Right/Left), 178°(Up/Down)

Backlight Dimming Technology
Global Dimming

Backlight Type
Edge

Brightness (Stabilization)
600cd/m²

Colour Depth (Number of Colours)
1.07B

Contrast Ratio (Typ.)
1000:1

Panel Type
IPS

Peak Brightness (Typ.)
800cd/m² (Peak)

Resolution
1920 x 1080

Size (Inch)
27

Surface Treatment
Protection Glass (1.6t, Anti-Reflection, Anti-fingerprint)

FEATURE

Hot Key
Yes (2keys)

Black Stabilizer
Yes

HW Calibration
Yes (True Color Pro)

Brightness stabilization
Yes

Factory Calibration
Yes (Delta E<5, Gamma 1.8~2.6/DICOM curve)



DICOM Compliant
Yes

<https://www.lg.com/uk/business/monitor/medical-display-device/surgical-monitors/27hk510s-w/>

27" LG Full HD Surgical Monitor







Features Gallery Specs Support Resource Find a Dealer [Contact Us](#)

FEATURE

Hot Key Yes (2keys)	Brightness stabilization Yes	Black Stabilizer Yes	Factory Calibration Yes (Delta E <5, Gamma 1.8~2.6/DICOM curve)
HW Calibration Yes (True Color Pro)	DICOM Compliant Yes	Colour Temperature 6500K/7500K/9300K Manual (5000K ~ 10000K)	Flicker safe Yes
OSD Language 17 Language	PBP  Yes (2PBP)	 PIP Yes	Picture Mode (SDR)Custom, Mono, sRGB, EBU, REC709, SMPTE-C, DICOM, Calibration 1, Calibration 2
Failover Input Switch Yes	Smart Energy Saving Yes	Super Resolution+ Yes	Uniformity Yes

8. Vaizdo perteikimas dviem
kanalais:
8.1. Vaizdas vaizde (PIP);
8.2. Vaizdas ne vaizde (PBP);

Available Accessories

	UG410	Earth Leakage Monitor, 200-240 V	for mounting to equipment carts, control panel dimensions: 44 x 80 x 29 mm (w x h x d), for use with Isolation Transformer UG310
	UG400	Earth Leakage Monitor, 100-120 V	for mounting to equipment carts, control panel dimensions: 44 x 80 x 29 mm (w x h x d), for use with Isolation Transformer UG300
	UG501	Monitor Holder Adaptor	for central mounting of monitor holding arms on the rear attachment points of the COR equipment carts UGxxx for use with UG500, UG510 and UG520
	UG540	Monitor Swivel Arm	height and side adjustable, can be positioned on the left or on the right side, swivel range 180°, reach 780 mm, from center 1170 mm, loading capacity max. 15 kg, with monitor mount VESA 75/100
	UG500	Monitor Holder	height adjustable, swiveling and tilting, swivel range approx. 360°, loading capacity max. 18 kg, with monitor mount VESA 75/100
	UG520	Monitor Holding Arm, long	height and side adjustable, tilting, swivel range approx. 320°, reach 760 mm, loading capacity max. 15 kg, with monitor mount VESA 75/100
	UG510	Monitor Holding Arm	height and side adjustable, tilting, can be mounted either on the left or on the right side, swivel range up to approx. 320°, reach 530 mm, loading capacity max. 15 kg, with monitor mount VESA 75/100

Į komplektaciją įeina reguliuojamo aukščio, pasukamas ir palenkiamas/paverčiamas vaizdo monitoriaus laikiklis tvirtinamas prie mobilaus vežimėlio – 1 vnt.

PRODUCT LAUNCH

TELECAM C3

1. Introduction: Background of the TELECAM C3

Whereas the IMAGE1 S™ system provides high-end imaging with options like 3D, 4K, fluorescence imaging, and hybrid applications, and small, compact solutions like the C-MAC® and the TELE PACK+ work well on specific applications and in areas with limited available space, there is also a need for solid, tower-based camera systems with good imaging that can be connected to a wide range of rigid and flexible endoscopes.

In the past, the TELECAM DX II/SL II met this need. However, since these camera systems are based on SD technology and have been on the market for a very long time, it was time to upgrade them to FULL HD to meet current imaging standards. System compatibility has also been greatly expanded to cover additional fields of application.

TELECAM C3

A Camera Control Unit Created for Rigid, Flexible and Single-Use Endoscopy

2. TELECAM C3

2.1 Technical features

	20233020/20213020 TELECAM DX II/SL II	TC100 TELECAM C3
Power supply	100-240 VAC	100-240 VAC
Line frequency	50/60 Hz	50/60 Hz
Resolution	Horizontal resolution > 450 lines SD	1920 x 1080 px (FHD)
Control	Keyboard, camera head buttons	Keyboard, camera head buttons
Compatibility	TELECAM camera heads <ul style="list-style-type: none"> Standard & pendulum D1 CCD video endoscopes	X-LINE <ul style="list-style-type: none"> TH110/TH111 TH115/TH116 CCD video endoscopes HD video endoscopes C-LINE <ul style="list-style-type: none"> TH130 C-LINE Single-use endoscopes
Memory	-	USB memory interface Internal memory size (~50GB)
Image format	-	JPEG
Video format	-	MPEG-4

1. „Full HD“ aukštos raiškos standartas;

10. Galimybė suvesti paciento duomenis;

5. Valdymas kameros galvos mygtukais;

11. Nuotraukų formatas JPEG.

LED Cold Light Fountains

POWER LED 175 SCB, LED NOVA 150



2. Su atskiru LED tipo
šviesos šaltiniu;

	20 1614 01-1 Cold Light Fountain POWER LED 175 SCB	20 1612 01 Cold Light Fountain LED NOVA 150
	with integrated KARL STORZ-SCB, high-performance LED module and one KARL STORZ light outlet	high-performance LED module, with one KARL STORZ light outlet
including:	Mains Cord SCB Connecting Cable	Mains Cord

Specifications:

Illumination technology	LED	
Color temperature	approx. 6400 K	
Average lamp service life	30,000 h	
Light intensity adjustment	automatic via SCB manual via SCB manual via membrane keyboard	manual
Unit communication	KARL STORZ Communication Bus (2x SCB)	–
Power consumption	110 VA	60 VA
Power supply	110 – 240 VAC	100 – 240 VAC
Power frequency	50/60 Hz	
Dimensions w x h x d	305 x 110 x 233 mm	305 x 84 x 238 mm
Weight	4 kg	2.3 kg
Cleaning	wipe disinfection	
Protection class	1	
Degree of safety	CF	

4. Rankinis apšvietimo
intensyvumo reguliavimas;



Item no: 20161201

LED Nova 150

Quantity:

— 1 +

On the offer list



Scope of delivery

20161220	LED Nova 150, without accessories (1)
400A	power cord, length 300 cm (1)

Product details

- Laser-free LED light source for white light excitation
- Constant light intensity throughout the entire service life
- Low temperature development
- Very low volume

3. Baltos šviesos režimas;

PRODUCT LAUNCH

TELECAM C3

2.2 Features and benefits

The TELECAM C3 is a FULL HD camera control unit (CCU) to be used with a basic endoscopy system. This CCU can be connected to a wide range of rigid, flexible, and single-use KARL STORZ endoscopes, making it usable in practically every medical discipline. The TELECAM C3 can be used in private practices as well as in surgical environments.

1. FULL HD CCU
2. Combination of X-LINE and C-LINE: compatible with rigid, flexible, and single-use KARL STORZ endoscopes
3. Allows patient data input ← 10. Galimybė suvesti paciento duomenis;
4. Store data to internal memory (up to 50 GB) or an external storage device
5. Improved* menu navigation thanks to newly developed navigation interface (see also TELE PACK+)

** in comparison with previous model*

Regarding 1. FULL HD CCU

The TELECAM C3 is the perfect CCU for a FULL HD imaging chain. When paired with the appropriate camera heads and video endoscopes, the TELECAM C3 provides image quality equivalent to that of the IMAGE1 S™ with the TC200 and the TC301. A FULL HD signal can be transmitted to monitors and documentation systems via the DVI output. An appropriate light source for the application in question completes the imaging chain.

TELECAM C3

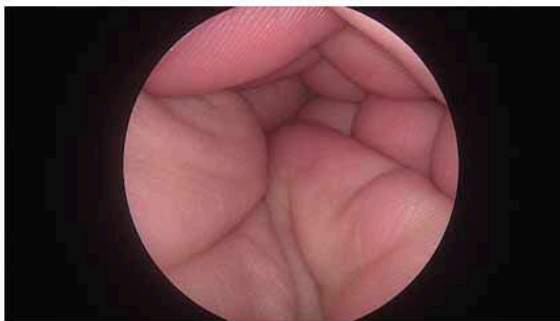
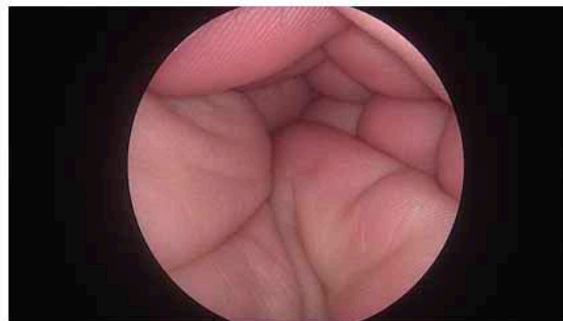


IMAGE1 S™



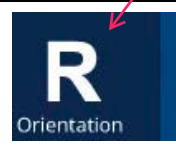
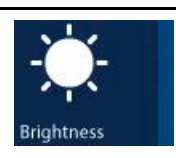


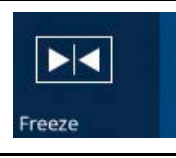




PRODUCT LAUNCH

TELECAM C3

The **Function Space** provides additional functions that are not assigned to the Quick Menu. Furthermore, the Function Space allows access to the **Setup menu**, where the general TELECAM C3 settings can be modified.

6. Valdymo meniu anglų kalba;

The following buttons and functions can be found in the Quick Menu and the Function Space:

	Orientation: The displayed image can be flipped vertically or horizontally and rotated 180° here.
	Camera brightness: The brightness of the camera can be set here.
	Enhance: The digital fiberscope filter can be set to 2 levels (A, B).
	Exit: You can exit the quick menu here.
	Freeze: You can freeze the image here. During this time, the live image is shown in the top right-hand corner of the monitor.
	Light: Here the light source can be turned on/off.
	Print now: Immediately prints all images in the queue.
	Light source: The light source settings can be displayed and modified here.
	Image capture: Still images can be captured here.





8. Vaizdo apvertimo funkcija;

9. Šviesumo režimo pasirinkimai;

8. Vaizdo sustabdymo funkcija;







PRODUCT LAUNCH

TELECAM C3

	Video: A video recording can be started here.
	Training Mode: A circle can be displayed in the center of the image here. The Training Mode can be used specifically for endoscopy training.
	White Balance: White Balance is executed here.
	Zoom: This enables digital magnification of the display.

7. Galimybė didinti endoskopinį vaizdą;

The Setup menu provides access to the following settings:

	Display language: The language of the user interface can be selected here.
	Keyboard language: The keyboard language of the on-screen keyboard can be selected here.
	DVI signal output: Here, you can select the image refresh rate between 50 Hz and 60 Hz for the DVI output.
	Date & time: The date, time, and display format can be set here.
	Patient management: The settings for handling patient data can be managed here.
	Module information: All the necessary information on the system and the connected camera heads and video endoscopes can be called up here.

PRODUCT LAUNCH

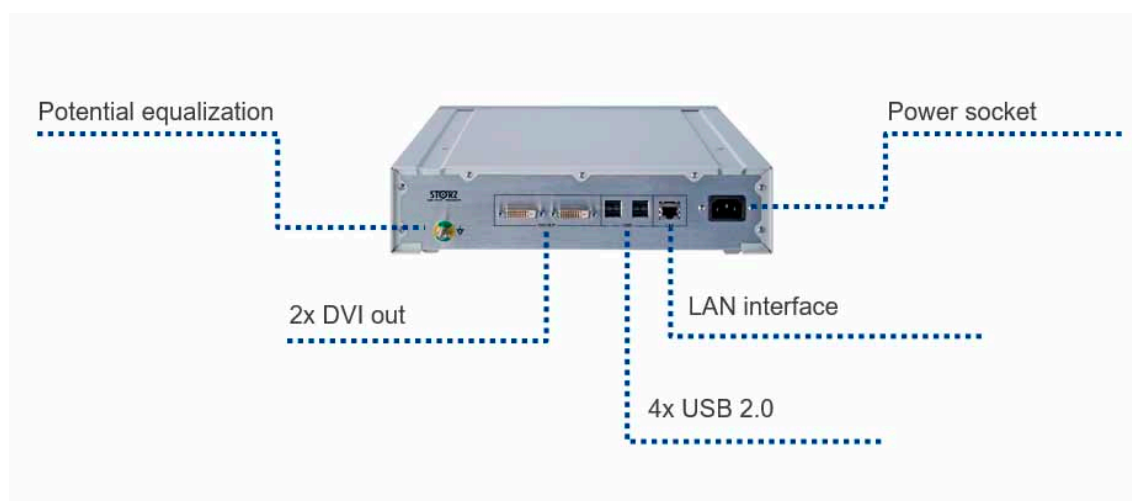
TELECAM C3

Functionality	<ul style="list-style-type: none"> Filter (fiberscope A+B) 	<ul style="list-style-type: none"> Filter (fiberscope A+B) Printer 549M Internal memory
Weight	~2.7 kg	~ 2.75 kg
Dimensions (w x h x d)	305 mm x 88 mm x 254 mm	305 mm x 77 mm x 339 mm
Connections	FBAS signal to BNC socket 2 x S-Video (Y/C) 2 x stereo 3.5 mm jack	2 x DVI-D output (FULL HD) USB to ACC USB footswitch socket RJ45 service interface

1. 1 x DVI;
2. 1 x DVI.



Front view of the TELECAM C3



Rear view of the TELECAM C3

Please note: the TELECAM C3 does not feature a KS HIVE connection.

Sample Model Variations from the COR Equipment Cart Series



UG210

Equipment Cart, wide, small, rides on 4 antistatic dual wheels equipped with locking brakes, mains switch on cover, energy beam with integrated electrical subdistributors with 6 sockets, grounding plugs,

Dimensions:

Equipment cart: 830 x 1265 x 730 mm (w x h x d),

Shelf: 630 x 25 x 510 mm (w x h x d),

Caster diameter: 150 mm

including:

Base Module, equipment cart, wide

Cover, equipment cart, wide

Beam Package, equipment cart, small

Shelf, wide

2x **Drawer Unit with Lock**, wide

2x **Equipment Rail**, long

1. Ratukai 4 vnt., keturi iš jų fiksuojami ir antistatiniai;
2. 2 vnt. lentynų;
3. 1 kanalas įrangos laidams paslėpti.



UG110

Equipment Cart, narrow, small, rides on 4 antistatic dual wheels equipped with locking brakes, mains switch on cover, energy beam with integrated electrical subdistributors with 6 sockets, grounding plugs,

Dimensions:

Equipment cart: 660 x 1265 x 730 mm (w x h x d),

Shelf: 450 x 25 x 510 mm (w x h x d),

Caster diameter: 150 mm

including:

Base Module, equipment cart, narrow

Cover, equipment cart, narrow





Beam Package, equipment cart, small

2x **Shelf**, narrow

Drawer Unit with Lock, narrow

2x **Equipment Rail**, long

Available Accessories

	UG610	Sliding Tray Holder, narrow	max. load 20 kg, Dimensions: 450 x 510 mm (w x d)
	UG611	Sliding Tray Holder, wide	max. load 20 kg, Dimensions: 630 x 510 mm (w x d)
	UG612	Camera Holder	<div> 1. Suderinamas su siūloma kameros galva. 2. Tvirtinasi prie siūlomo mobilaus vežimėlio. </div> for storing camera heads, with detachable inlays, compatible with all KARL STORZ endoscopy camera heads
	UG613	Holder, for support element	for mounting Bottle Stand Holder 20300033
	UG614	Counterweight Plate	for improved stability in combination with a monitor holding arm, Dimensions: 356 x 6 x 478 mm (w x h x d)
	UG615	Auxiliary Counterweight Plate	for improved stability in combination with a monitor holding arm, Dimensions: 290 x 6 x 478 mm (w x h x d)

STORZ

KARL STORZ—ENDOSKOPE



GEBRAUCHSANWEISUNG

UH 400/400 U/401/401 U Hochfrequenz-Chirurgiegerät AUTOCON® III 400



INSTRUCTION MANUAL

UH 400/400 U/401/401 U High frequency surgical unit AUTOCON® III 400



MANUAL DE INSTRUCCIONES

UH 400/400 U/401/401 U Aparato quirúrgico de alta frecuencia AUTOCON® III 400



3 Beschreibung

3.1 Anzeige- und Bedienelemente

3.1.1 Bedienelemente der Vorderseite

3 Description

3.1 Display and control elements

3.1.1 Control elements on the front panel

3 Descripción

3.1 Elementos de indicación y de mando

3.1.1 Elementos de mando de la parte delantera



i Die Aktivierungsbalken (7 - 10) leuchten gelb oder blau auf, sobald ein Instrument an der zugehörigen Buchse aktiviert wird.

i While activating an instrument, the activation bar (7 - 10) of the corresponding socket illuminates yellow or blue.

i La barra de activación (7 - 10) se enciende de color amarillo o azul tan pronto como se activa un instrumento en el conector correspondiente.

- ① Standby-Taster (EIN – weiß umleuchtet)
- ② Symbol »Standby Taster«
- ③ Neutralelektrode bei HF von Erde isoliert
- ④ Symbol »Defibrillationsgeschütztes Anwendungsteil des Typs CF«
- ⑤ Symbol »Gebrauchsanweisung befolgen«
- ⑥ Touchscreen mit Aktivierungstasten der Modi
- ⑦ Aktivierungsbalken obere unipolare Buchse
- ⑧ Aktivierungsbalken untere unipolare Buchse
- ⑨ Aktivierungsbalken obere bipolare Buchse
- ⑩ Aktivierungsbalken untere bipolare Buchse

- ① Standby button (ON – surrounded by a white light)
- ② Symbol 'Standby button'
- ③ Neutral electrode isolated from ground for HF
- ④ Symbol 'CF type applied part with defibrillation protection'
- ⑤ Symbol 'Observe instruction manual'
- ⑥ Touch screen with mode selection buttons
- ⑦ Activation bar upper unipolar socket
- ⑧ Activation bar lower unipolar socket
- ⑨ Activation bar upper bipolar socket
- ⑩ Activation bar lower bipolar socket


- ① Pulsador standby (CON. – rodeado por anillo iluminado)
- ② Símbolo "Pulsador standby"
- ③ Electrodo neutro para AF aislado de tierra
- ④ Símbolo "Pieza de aplicación protegida contra desfibrilación de la clase CF"
- ⑤ Símbolo "Consultar el Manual de instrucciones"
- ⑥ Pantalla táctil con teclas de activación de los modos
- ⑦ Barra de activación del conector unipolar superior
- ⑧ Barra de activación del conector unipolar inferior
- ⑨ Barra de activación del conector bipolar superior
- ⑩ Barra de activación del conector bipolar inferior

3.1. 14 monopolinių pjovimo režimų;

5.6 Modus-Übersicht

Im Folgenden erhalten Sie eine Übersicht über die mit dem HF-Gerät ausführbaren Stromarten.

5.6.1 Unipolare Modi












Bildzeichen Modus Schneiden	Bezeichnung
	Laparoskopie
	Standard
	Mikro
	Resektion
	Resektion C-Cut®
	SupraLoop
	Trocken
	Gastro Loop 1
	Gastro Loop 2
	Gastro Loop 3
	Gastro Knife 1

3.4. 6 pulsuoiantys monopoliniai režimai darbui su endoskopu

5.6 Mode overview

An overview of the current types that can be executed with the HF device is shown below.



5.6.1 Unipolar modes

Cutting mode symbol	Designation
	Laparoscopy
	Standard
	Micro
	Resection
	Resection C-Cut®
	SupraLoop
	Dry
	Gastro Loop 1
	Gastro Loop 2
	Gastro Loop 3
	Gastro Knife 1

5.6 Vista general de los modos

A continuación se expone una vista general de los tipos de corriente que pueden ejecutarse con el aparato de AF.

5.6.1 Modos unipolares










Pictograma de modo Corte	Denominación
	Laparoscopia
	Estándar
	Micro
	Resección
	Resección C-Cut®
	SupraLoop
	Seco
	Gastro Loop 1
	Gastro Loop 2
	Gastro Loop 3
	Gastro Knife 1










3.2. 14 monopolinēs
koagulācijas režīmū;

Bildzeichen Modus Schneiden	Bezeichnung
	Gastro Knife 2
	Gastro Knife 3
	Argon*

Cutting mode symbol	Designation
	Gastro Knife 2
	Gastro Knife 3
	Argon*

Pictograma de modo Corte	Denominación
	Gastro Knife 2
	Gastro Knife 3
	Argón*

Bildzeichen Modus Koagulieren	Bezeichnung
	Laparoskopie
	Moderat
	Forciert coag
	Resektion
	Spray
	Forciert mixed
	Forciert cutting
	Gastro Coag
	Argon flexibel*






Coagulation mode symbol	Designation
	Laparoscopy
	Moderate
	Forced coag
	Resection
	Spray
	Forced mixed
	Forced cutting
	Gastro Coag
	Argon flexible*

Pictograma de modo Coagulación	Denominación
	Laparoscopia
	Moderado
	Coag. forzada
	Resección
	Spray
	Forzado mezclado
	Corte forzado
	Gastro Coag
	Argón flexible*






Bedienung

Operation


Manejo

Bildzeichen Modus Koagulieren	Bezeichnung
	Argon flex. Puls*
	Argon offen*
	Cardiac Thorax
	Cardiac Mammaria
	SimCoag

i * Diese Modi sind in nur Verbindung mit einem Argon-Beamer aktivierbar. Unser Service informiert Sie gerne über die zur Verfügung stehenden Kombinationsmöglichkeiten.

Coagulation mode symbol	Designation
	Argon flex. pulse*
	Argon open*
	Cardiac Thorax
	Cardiac Mammary
	SimCoag

i * These modes can only be activated in combination with an Argon beamer. Our service team will be happy to provide you with information on the available combination options.





Pictograma de modo Coagulación	Denominación
	Argón flex. puls*
	Argón abierto*
	Cardíaco tórax
	Cardíaco mamaria
	SimCoag

i * Estos modos solamente pueden activarse en combinación con un coagulador de argón. Si así lo desea, nuestro Servicio Técnico le informará con mucho gusto de las posibles combinaciones disponibles.





5.6.2 Bipolare Modi

Bildzeichen Modus Schneiden	Bezeichnung
	Bip. Schneiden
	Bipolare Schere
	Bip. Resektion
	Bip. Vaporisation








5.6.2 Bipolar modes








Cutting mode symbol	Designation
	Bip. cutting
	Bipolar scissors
	Bip. resection
	Bip. vaporization

5.6.2 Modos bipolares





Pictograma de modo Corte	Denominación
	Corte bip.
	Tijeras bipolares
	Resección bip.
	Vaporización bip.

**3.3. 9 bipolīnēs
koaguliācijas režīmai;**

Bildzeichen Modus Koagulieren	Bezeichnung
	RoBi®
	Laparoskopie
	Standard
	Bip. Resektion
	Bip. Vaporisation
	BiVascularSafe*
	BiVascularSafe Open Surgery*





Coagulation mode symbol	Designation
	RoBi®
	Laparoscopy
	Standard
	Bip. resection
	Bip. vaporization
	BiVascularSafe*
	BiVascularSafe Open Surgery*

Pictograma de modo Coagulación	Denominación
	RoBi®
	Laparoscopia
	Estándar
	Resección bip.
	Vaporización bip.
	BiVascularSafe*
	BiVascularSafe Open Surgery*

Bildzeichen Modus Koagulieren	Bezeichnung
	Standard AUTO
	Bipolare Schere
	Mikro
	Forciert


i * Diese Modi sind verfügbar bei der Geräteversion UH 401 und UH 401U.

Die Angaben über Einstellwerte, Applikationsstellen, Applikationsdauer und den Gebrauch der Instrumentarien beruhen auf klinischen Erfahrungen. Es handelt sich jedoch lediglich um Richtwerte, die von dem Operateur auf ihre Anwendbarkeit geprüft werden müssen. Abhängig von den individuellen Gegebenheiten kann es erforderlich sein, von den Angaben abzuweichen. Infolge von Forschung und klinischen Erfahrungen ist die Medizin ständigen Entwicklungen unterworfen. Auch daraus kann sich ergeben, dass eine Abweichung von den hier enthaltenen Angaben sinnvoll sein kann.

Coagulation mode symbol	Designation
	Standard AUTO
	Bipolar scissors
	Micro
	Forced

i * These modes are available for the device versions UH 401 and UH 401U.

The information and data regarding settings, application points, application duration and instrument use are based on clinical practice. However, these are only basic guidelines which must be tested for suitability by the operator. Depending on individual conditions, it may be necessary to deviate from the provided data. Medical practice is continuously evolving as a result of R&D and clinical experience. This may also make deviations from the provided data necessary.

Pictograma de modo Coagulación	Denominación
	Standard AUTO
	Tijeras bipolares
	Micro
	Forzada

i * Estos modos están disponibles con las versiones del aparato UH 401 y UH 401U.

Los datos relativos a valores de ajuste, lugares de aplicación, duración de la aplicación y empleo de instrumental están basados en experiencias clínicas. No obstante, constituyen meros valores orientativos y el cirujano ha de comprobar que sean aplicables. En función de las circunstancias específicas, puede resultar necesario desviarse de estos datos. La medicina está sujeta a un desarrollo constante como consecuencia de la investigación y de la experiencia clínica. Ello también puede tener como resultado que posiblemente sea recomendable desviarse de los datos aquí indicados.

5.7 Unipolare Modi Schneiden

5.7.1 Laparoskopie



Dieser Modus wird in der Laparoskopie und Arthroskopie zum unipolaren Schneiden verwendet.

Anwendungsgebiete

Laparoskopie, Arthroskopie

Geeignete Instrumente

- Arthroskopie-Elektroden
- Laparoskopie-Elektroden

5.7.2 Standard



In diesem Modus wird ein leistungsstarker HF-Strom mit geringem Crestfaktor für Schnitte in biologischem Gewebe eingesetzt.

Die Lichtbogenregelung des ARC CONTROL passt die Leistungsabgabe bei Gewebeunterschieden und Veränderungen von Schnittfläche oder -geschwindigkeit auf das erforderliche Minimum an.

Anwendungsgebiete

Schneiden mit niedrigem elektrischem Gewebewiderstand, z. B. Muskelgewebe oder vaskularisiertes Gewebe

Schneiden oder Präparieren von feinen Strukturen

Geeignete Instrumente

- Nadelelektroden
- Messerelektroden
- Spatulelektroden
- Schlingenelektroden

5.7 Unipolar cutting modes

5.7.1 Laparoscopy



This mode is used in laparoscopy and arthroscopy for unipolar cutting.

Application areas

Laparoscopy, arthroscopy

Suitable instruments

- Arthroscopy electrodes
- Laparoscopy electrodes

5.7.2 Standard



In this mode a high-performance HF current with a low crest factor is used for cutting biological tissue.

ARC CONTROL adjusts the power output to the minimum required level in response to variations in tissue type and changes in the cutting area or speed.

Application areas

Cutting tissue with low electrical resistance, such as muscle tissue or vascular tissue.

Cutting or preparing fine structures

Suitable instruments

- Needle electrodes
- Knife electrodes
- Spatula electrodes
- Loop electrodes

5.7 Modos unipolares Corte

5.7.1 Laparoscopia



Este modo se emplea con fines de corte unipolar en laparoscopia y artroscopia.

Campos de aplicación

Laparoscopia, artroscopia

Instrumentos apropiados

- Electrodo para artroscopia
- Electrodo para laparoscopia

5.7.2 Estándar



En este modo se emplea una corriente de AF de gran potencia con factor de cresta muy reducido para practicar cortes en tejido biológico.

La regulación del arco voltaico del ARC CONTROL adapta la potencia suministrada, reduciéndola al mínimo necesario, a las diferentes características del tejido y los cambios en cuanto a la superficie o la velocidad de corte.

Campos de aplicación

Corte de tejidos con baja resistencia eléctrica como, p. ej., tejido muscular o vascularizado.

Corte o preparación de estructuras finas

Instrumentos apropiados

- Electrodo de aguja
- Electrobisturios
- Electrodo de espátula
- Electrodo de asa

4. Instaliuota galios savireguliacijos funkcija (priklausomai nuo pjaunamo audinio varžos);

5.7.7 Trocken



Dieser Modus dient zum unipolaren trockenen Schneiden. Durch die Erzeugung eines großen geregelten Lichtbogens kann eine deutlich tiefere Koagulation erreicht werden.

Anwendungsgebiete

Herzchirurgie, Blutstillung von zurückweichenden Blutgefäßen im Bereich des Sternums

Geeignete Instrumente

- Messerelektroden

5.7.8 Gastro Loop 1



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt. Mit Polypektomieschlingen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Der Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der eher langsamen Pulsfolge von 1 Schneidimpuls pro Sekunde ist dieser Modus für besonders vorsichtiges Arbeiten geeignet.

Anwendungsgebiete

Abtragen von Polypen mit Polypektomieschlingen über flexible Endoskope

Geeignete Instrumente

- Polypektomieschlingen

5.7.7 Dry



This mode is used for unipolar dry cutting. A large, controlled arc is generated, which allows significantly deeper coagulation to be obtained.

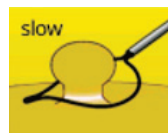
Application areas

Cardiac surgery and blood coagulation in retracting blood vessels in the sternum region.

Suitable instruments

- Knife electrodes

5.7.8 Gastro Loop 1



- This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a relatively slow pulse rate of 1 cutting pulse per second, this mode is suitable for especially cautious work.

Application areas

Polyp removal using polypectomy snares and flexible endoscopy.

Suitable instruments

- Polypectomy snares

5.7.7 Seco



Este modo sirve para practicar un corte seco unipolar. Generando un arco voltaico regulado de gran tamaño puede obtenerse una coagulación notablemente más profunda.

Campos de aplicación

Cirugía cardíaca, hemostasia de vasos sanguíneos con retracción en el área del esternón.

Instrumentos apropiados

- Electrobisturías

5.7.8 Gastro Loop 1



Este modo se emplea en la especialidad de gastroenterología. Para cortar y coagular se utilizan asas para polipectomía. La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. El modo consta de una serie de impulsos de corriente de corte y fase de coagulación. Con la serie de impulsos más bien lenta, de 1 impulso de corte por segundo, este modo es idóneo para operaciones que requieran particular cuidado.

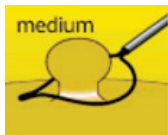
Campos de aplicación

Extirpación de pólipos con asas para polipectomía utilizadas con endoscopios flexibles

Instrumentos apropiados

- Asas para polipectomía

5.7.9 Gastro Loop 2



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt.

Mit Polypektomieschlingen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Der Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der dynamischen Pulsfolge von 1,5 Schneidimpulsen pro Sekunde ist dieser Modus für geübte Anwender geeignet.

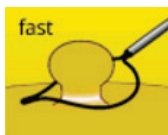
Anwendungsgebiete

Abtragen von Polypen mit Polypektomieschlingen über flexible Endoskope, dynamische Pulsfolge für geübte Anwender

Geeignete Instrumente

- Polypektomieschlingen

5.7.10 Gastro Loop 3



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt. Mit Polypektomieschlingen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Der Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der dynamischen und schnellen Pulsfolge von 2,2 Schneidimpulsen pro Sekunde ist dieser Modus für sehr versierte Anwender geeignet.

Anwendungsgebiete

Abtragen von Polypen mit Polypektomieschlingen über flexible Endoskope, dynamische schnelle Pulsfolge für versierte Anwender

Geeignete Instrumente

- Polypektomieschlingen

5.7.9 Gastro Loop 2



- This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a dynamic pulse rate of 1.5 cutting pulses per second this mode is suited to experienced users.

Application areas

Polyp removal using polypectomy snares and flexible endoscopy, with dynamic pulse rate for experienced users.

Suitable instruments

- Polypectomy snares

5.7.10 Gastro Loop 3



- This mode is used in gastroenterology. Polypectomy snares are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a dynamic and fast pulse rate of 2.2 cutting pulses per second, this mode is suitable for advanced users.

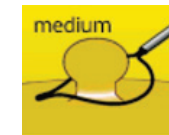
Application areas

Polyp removal using polypectomy snares and flexible endoscopy, with dynamic fast pulse rate for advanced users.

Suitable instruments

- Polypectomy snares

5.7.9 Gastro Loop 2



Este modo se emplea en la especialidad de gastroenterología.

Para cortar y coagular se utilizan asas para polipectomía. La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. El modo consta de una serie de impulsos de corriente de corte y fase de coagulación. Al suministrar una frecuencia dinámica de 1,5 impulsos de corte por segundo, este modo es idóneo para usuarios experimentados.

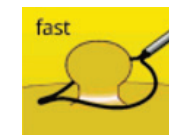
Campos de aplicación

Extirpación de pólipos con asas para polipectomía utilizadas con endoscopios flexibles, frecuencia dinámica para usuarios experimentados

Instrumentos apropiados

- Asas para polipectomía

5.7.10 Gastro Loop 3



Este modo se emplea en la especialidad de gastroenterología. Para cortar y coagular se utilizan asas para polipectomía. La regulación del arco voltaico genera el efecto de corte suministrando al mismo tiempo la mínima potencia necesaria. El modo consta de una repetición de impulsos de fase de corriente de corte y coagulación. Al suministrar una frecuencia dinámica y rápida de 2,2 impulsos de corte por segundo, este modo es idóneo para usuarios muy experimentados.

Campos de aplicación

Extirpación de pólipos con asas para polipectomía utilizadas con endoscopios flexibles, frecuencia dinámica rápida para usuarios muy experimentados

Instrumentos apropiados

- Asas para polipectomía

5.7.11 Gastro Knife 1



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt. Mit Instrumenten für die Papillotomie und endoskopische Resektionen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Dieser Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der eher langsamen Pulsfolge von 1,3 Schneidimpulsen pro Sekunde ist dieser Modus für besonders vorsichtiges Arbeiten geeignet.

Anwendungsgebiete

Einschneiden von Papillen mit einem Papillotom über flexible Endoskope, Resektion mit Nadelmessern, langsame Pulsfolge für vorsichtiges Arbeiten.

Geeignete Instrumente

- Papillotome
- Nadelmesser

5.7.12 Gastro Knife 2



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt. Mit Instrumenten für die Papillotomie und endoskopische Resektionen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Dieser Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der dynamischen Pulsfolge von 1,8 Schneidimpulsen pro Sekunde ist dieser Modus für geübte Anwender geeignet.

5.7.11 Gastro Knife 1



- This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a relatively slow pulse rate of 1.3 cutting pulses per second, this mode is suitable for especially cautious work.

Application areas

Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; slow pulse rate for cautious work.

Suitable instruments

- Papillotomes
- Needle knives

5.7.12 Gastro Knife 2



- This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a dynamic pulse rate of 1.8 cutting pulses per second, this mode is suitable for experienced users.

5.7.11 Gastro Knife 1



Este modo se emplea en la especialidad de gastroenterología. Para practicar el corte y la coagulación se utilizan instrumentos para papilotomía y resecciones endoscópicas. La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. Este modo consta de una serie de impulsos de corriente de corte y fase de coagulación. Al suministrar una frecuencia más bien lenta, de 1,3 impulsos de corte por segundo, este modo es idóneo para operaciones que requieran particular cuidado.

Campos de aplicación

Corte de papilas con un papilótomo utilizado con endoscopios flexibles, resección con bisturíes de aguja, frecuencia lenta de impulsos para operaciones que requieran particular cuidado.

Instrumentos apropiados

- Papilótomos
- Bisturíes de aguja

5.7.12 Gastro Knife 2



Este modo se emplea en la especialidad de gastroenterología. Para practicar el corte y la coagulación se utilizan instrumentos para papilotomía y resecciones endoscópicas. La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. Este modo consta de una serie de impulsos de corriente de corte y fase de coagulación. Al suministrar una frecuencia dinámica de 1,8 impulsos de corte por segundo, este modo es idóneo para usuarios experimentados.

Anwendungsgebiete

Einschneiden von Papillen mit einem Papillotom über flexible Endoskope, Resektion mit Nadelmessern, dynamische Pulsfolge für geübte Anwender.

Geeignete Instrumente

- Papillotome
- Nadelmesser

5.7.13 Gastro Knife 3



Dieser Modus wird im Bereich der Gastroenterologie eingesetzt. Mit Instrumenten für die Papillotomie und endoskopische Resektionen wird geschnitten und koaguliert. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. Dieser Modus besteht aus einer Pulsfolge von Schneidstrom und Koagulationsphase. Mit der dynamischen und schnellen Pulsfolge von 2,2 Schneidimpulsen pro Sekunde ist dieser Modus für sehr versierte Anwender geeignet.

Anwendungsgebiete

Einschneiden von Papillen mit einem Papillotom über flexible Endoskope, Resektion mit Nadelmessern, dynamische schnelle Pulsfolge für versierte Anwender.

Geeignete Instrumente

- Papillotome
- Nadelmesser

Application areas

Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; dynamic pulse rate for experienced users.

Suitable instruments

- Papillotomes
- Needle knives

5.7.13 Gastro Knife 3



- This mode is used in gastroenterology. Instruments for papillotomy and endoscopic resections are used for cutting and coagulation. Arc control generates the cutting effect with simultaneously minimized output power. This mode consists of a series of cutting current pulses followed by a coagulation phase. With a dynamic and fast pulse rate of 2.2 cutting pulses per second, this mode is suitable for advanced users.

Application areas

Papilla incision using a papillotome and flexible endoscopy, resection with needle knives; dynamic fast pulse rate for advanced users.

Suitable instruments

- Papillotomes
- Needle knives

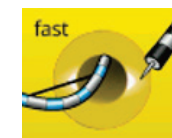
Campos de aplicación

Corte de papilas con un papilótomo utilizado con endoscopios flexibles, resección con bisturíes de aguja, frecuencia dinámica de impulsos para usuarios experimentados.

Instrumentos apropiados

- Papilótomos
- Bisturíes de aguja

5.7.13 Gastro Knife 3



Este modo se emplea en la especialidad de gastroenterología. Para practicar el corte y la coagulación se utilizan instrumentos para papilotomía y resecciones endoscópicas. La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. Este modo consta de una serie de impulsos de corriente de corte y fase de coagulación. Al suministrar una frecuencia dinámica y rápida de 2,2 impulsos de corte por segundo, este modo es idóneo para usuarios muy experimentados.

Campos de aplicación

Corte de papilas con un papilótomo utilizado con endoscopios flexibles, resección con bisturíes de aguja, frecuencia dinámica rápida de impulsos para usuarios experimentados.

Instrumentos apropiados

- Papilótomos
- Bisturíes de aguja

5.9.3 Bip. Resektion



Dieser bipolare Modus wird in der Gynäkologie und in der Urologie bei der Resektion mit Schlingenelektroden unter leitfähiger Spülflüssigkeit (Kochsalzlösung) eingesetzt. Die Lichtbogenregelung erzeugt den Schnitteffekt bei gleichzeitig minimierter Leistungsabgabe. ARC-Control bewirkt unverzügliches Schneiden und vermeidet ein Verkleben der Elektrode.

i Auf die Verwendung von NaCl als Spülflüssigkeit achten.

Während der Anwendung eine Dauerspülung durchführen.

Ausschließlich leitfähiges Gleitgel verwenden, da ansonsten Schädigungen der Harnröhre auftreten können.

Daueraktivierungen vermeiden.

Anwendungsgebiete

Hysteroskopie, Transurethrale Resektion Prostata (TUR-P), Operative Behandlung von Blasen Tumoren (TUR-BT).

Geeignete Instrumente

- Resektoskop (bipolar)
- Resektionsschlinge

i Optimale Ergebnisse sind ausschließlich bei der Verwendung des codierten KARL STORZ Resektionskabels möglich.

5.9.3 Bip. resection



This bipolar mode is used in gynecology and in urology for resection with loop electrodes under conductive irrigant solution (saline). Arc control generates the cutting effect with simultaneously minimized output power. ARC Control facilitates direct cutting and prevents electrode adhesion.

i Make sure that NaCl is used as an irrigation medium.

Secure a continuous irrigation during the application.

Always use conductive lubricants to avoid damages of the urethra.

Avoid continuous activations.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-BT).

Suitable instruments

- Resectoscope (bipolar)
- Resection loop

i Optimum results are possible only when using the coded KARL STORZ resection cable.

5.9.3 Resección bip.



Este modo bipolar se utiliza en ginecología y urología para practicar una resección con electrodos de asa usando líquido de irrigación conductivo (solución fisiológica salina). La regulación del arco voltaico genera el efecto de corte, suministrando al mismo tiempo la mínima potencia necesaria. ARC Control produce cortes inmediatos y evita que el electrodo quede adherido.

i Asegúrese de que se utiliza NaCl como líquido de irrigación.

Asegúrese de que la irrigación es continua durante la aplicación.

Utilice siempre lubricantes conductivos para evitar lesiones en la uretra.

Evite activaciones continuas.

Campos de aplicación

Hysteroscopia, resección transuretral de la próstata (RTU-P), tratamiento quirúrgico de tumores vesicales (RTU-TV).

Instrumentos apropiados

- Resectoscopio (bipolar)
- Asa de resección

i Para obtener resultados óptimos es indispensable utilizar el cable de resección KARL STORZ codificado.

5.9.4 Bip. Vaporisation



Dieser bipolare Modus wird in der Gynäkologie und in der Urologie bei der Vaporisation eingesetzt. Bei Gewebekontakt findet unmittelbar die Zündung des Lichtbogens statt was eine zügige Gewebevaporisation mit geringer Wärmeausbreitung in die Umgebung ermöglicht.

- i** Auf die Verwendung von NaCl als Spülflüssigkeit achten. Während der Anwendung eine Dauerspülung durchführen. Ausschließlich leitfähiges Gleitgel verwenden, da ansonsten Schädigungen der Harnröhre auftreten können. Daueraktivierungen vermeiden.

Anwendungsgebiete

Hysteroskopie, Transurethrale Resektion Prostata (TUR-P), Operative Behandlung von Blasen Tumoren (TUR-BT), Vaporisation des Prostatagewebes (TUR-VAP).

Geeignete Instrumente

- Resektoskop (bipolar)
- Vaporisations-Elektrode

Bipolare Scheren nur mit den Stromformen Bipolare Schere Schneiden bzw. Koagulieren betreiben.

5.10 Bipolare Modi Koagulieren

5.10.1 RoBi®



Dieser Modus speziell für RoBi® wird zur Koagulation in Verbindung mit bipolaren laparoskopischen Instrumenten eingesetzt.

■ 5.9.4 Bip. vaporization



This bipolar mode is used in gynecology and urology with vaporization. Upon tissue contact the arc is ignited directly resulting in rapid tissue vaporization with minimal heat emission to the surrounding area.

- i** Make sure that NaCl is used as an irrigation medium. Secure a continuous irrigation during the application. Always use conductive lubricants to avoid damages of the urethra. Avoid continuous activations.

Application areas

Hysteroscopy, transurethral prostate resection (TUR-P), surgical treatment of bladder tumors (TUR-BT), vaporization of prostate tissue (TUR-VAP).

Suitable instruments

- Resectoscope (bipolar)
- Vaporization electrode

Bipolar scissors should only be operated with the current type bipolar scissors for cutting or coagulation.

5.10 Bipolar coagulation modes

5.10.1 RoBi®



This mode designed specially for RoBi® is used for coagulation in combination with bipolar laparoscopic instruments.

5.9.4 Vaporización bip.



Este modo bipolar se utiliza para la vaporización en ginecología y urología. Al entrar en contacto con tejido, inmediatamente tiene lugar la formación del arco voltaico, lo que permite una rápida vaporización del tejido con escasa dispersión de calor en el entorno.

- i** Asegúrese de que se utiliza NaCl como líquido de irrigación. Asegúrese de que la irrigación es continua durante la aplicación. Utilice siempre lubricantes conductivos para evitar lesiones en la uretra.

Evite activaciones continuas.

Campos de aplicación

Histeroscopia, resección transuretral de la próstata (RTU-P), tratamiento quirúrgico de tumores vesicales (RTU-TV), vaporización de tejido de la próstata (RTU-VAP).

Instrumentos apropiados

- Resectoscopio (bipolar)
- Electrodo de vaporización

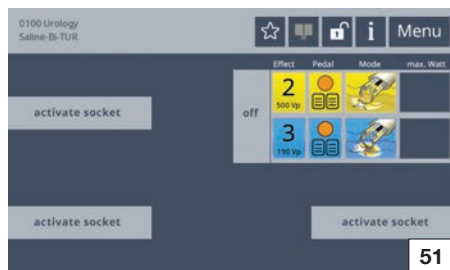
Utilice tijeras bipolares solamente con los tipos de corriente Corte o Coagulación bipolar Tijeras bipolares.

5.10 Modos de coagulación bipolar

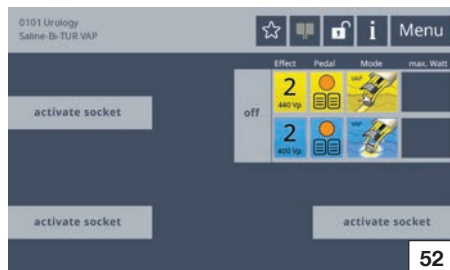
5.10.1 RoBi®



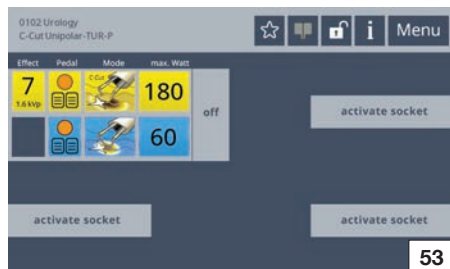
Este modo específico para RoBi® se utiliza para la coagulación en combinación con instrumentos laparoscópicos bipolares.



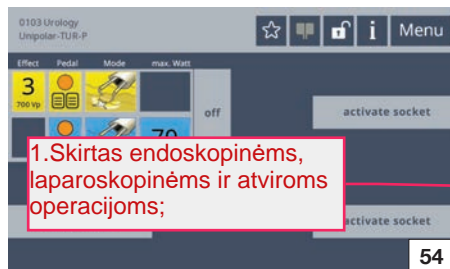
51



52



53



54

1. Skirtas endoskopinems, laparoskopinems ir atviroms operacijoms;

5.11.12 Basis-Programme (Prozeduren)

Prozeduren sind Programme, in denen Parameter wie Spannung und Leistung, für fachgebiets-spezifische, medizinische Eingriffe festgelegt sind. Sie können entweder eigene Prozeduren/ Programme erstellen (siehe Abschnitt 5.11.8) oder auf von KARL STORZ definierte Prozeduren zurückgreifen. Diese Prozeduren sind unterschiedlichen Fachgebieten, wie z. B. Urologie, Laparoskopie usw. zugeordnet und beginnen mit der Nummer 0100. Standardmäßig (Auslieferungszustand) sind alle fachgebietsspezifischen KARL STORZ Prozeduren/Programme sowie ein Standard-Programm freigeschaltet (sichtbar). Diese Programme sowie neu erstellte können nicht verändert oder gelöscht werden (außer die entsprechende Einstellung im Menü Service-Program Restrictions – Abschnitt 5.11.4 – wurde geändert). In diesem Menü können Sie auch die Fachgebiets-prozeduren »anwendergerecht« ein-/ausblenden.

Zur Auswahl siehe Abschnitt 5.11.6 Menü »Programme«.

i Der Prozedurname ist jeweils in der Statuszeile angezeigt (siehe Abschnitt 5.2.2).

Beim AUTOCON® III 400 sind die werkseitig eingestellten vordefinierten Prozeduren/Programme in folgende Benutzergruppen eingeteilt:

- Fachgebiet Urologie (0100-0105; siehe Abb. 51 bis 56)
- Fachgebiet Gynäkologie (0200-0208; siehe Abb. 57 bis 64)
- Fachgebiet Laparoskopie (0300-0303; siehe Abb. 65 bis 68); Prozedur 0303: BiVascularSafe nur bei Modellen UH 401 und UH 401U möglich
- Fachgebiet Gastroenterologie (0400-0401; siehe Abb. 69 bis 70)
- Anwendungsbereich offene Chirurgie (0500-0501; siehe Abb. 71 bis 72) Prozedur 0501: BiVascularSafe nur bei Modellen UH 401 und UH 401U möglich
- Fachgebiet Pädiatrie (0600; siehe Abb. 73)

5.11.12 Basic programs (procedures)

Procedures are programs in which parameters such as voltage and output are determined for specialist medical interventions. You can either create your own procedures/ programs (see section 5.11.8) or use procedures defined by KARL STORZ. These procedures are assigned to different disciplines, e.g. urology, laparoscopy and start with the number 0100. All specialist KARL STORZ procedures/programs and a standard program are enabled (visible) as standard (upon delivery). These programs and newly created ones cannot be changed or deleted (unless the corresponding setting in the menu Service – Program Restrictions, section 5.11.4, has been changed). In this menu you can display/ hide the specialist procedures to suit your needs. For selection see section 5.11.6 Menu 'Programs'.

i The procedure name is displayed in the status bar (see section 5.2.2).

The predefined procedures/programs set in the factory for the AUTOCON® III 400 are divided into the following user groups:

- Specialization urology (0100-0105; see Fig. 51 to 56)
- Specialization gynecology (0200-0208; see Fig. 57 to 64)
- Specialization laparoscopy (0300-0303; see Fig. 65 to 68); Procedure 0303: BiVascularSafe only possible with models UH 401 and UH 401U
- Specialization gastroenterology (0400-0401; see Fig. 69 to 70)
- Application open surgery (0500-0501; see Fig. 71 to 72) Procedure 0501: BiVascularSafe only possible with models UH 401 and UH 401U
- Specialization pediatrics (0600; see Fig. 73)

5.11.12 Programas básicos (procedimientos)

Los procedimientos son programas en los que parámetros tales como tensión y potencia se han determinado de forma fija para intervenciones médicas en especialidades específicas. Usted puede generar sus propios procedimientos/ programas (véase la sección 5.11.8) o utilizar los procedimientos definidos por KARL STORZ. Estos procedimientos están asignados a diferentes especialidades, tales como urología, laparoscopia, etc., y comienzan con el número 0100. De forma estándar (estado de suministro) están habilitados (visibles) todos los procedimientos/programas KARL STORZ específicos de especialidades, así como un programa estándar. Estos programas, así como otros creados nuevos, no pueden ser modificados o borrados (salvo que se haya modificado el ajuste correspondiente en el menú Servicio – Restricciones de programa – sección 5.11.4 –). En este menú también puede insertar/ocultar los procedimientos de especialidades conforme a los deseos del usuario.

Con respecto a la selección, véase la sección 5.11.6 del menú "Programas".

i El nombre del procedimiento aparece indicado en cada caso en la línea de estado (véase la sección 5.2.2).

Los procedimientos/programas predefinidos ajustados de fábrica en el AUTOCON® III 400 están distribuidos en los siguientes grupos de usuario:

- Especialidad de urología (0100-0105; véanse las figs. 51-56)
- Especialidad de ginecología (0200-0208; véanse las figs. 57-64)
- Especialidad de laparoscopia (0300-0303; véanse las figs. 65-68); Procedimiento 0303: BiVascularSafe solamente puede aplicarse en los modelos UH 401 y UH 401U
- Especialidad de gastroenterología (0400-0401; véanse las figs. 69-70)
- Campo de aplicación de cirugía abierta (0500-0501; véanse las figs. 71-72) Procedimiento 0501: BiVascularSafe solamente puede aplicarse en los modelos UH 401 y UH 401U
- Especialidad de pediatría (0600; véase la fig. 73)

10 Technische Daten

**10.1 Technische Daten für
AUTOCON® III 400**

Isolationsart/Klassifikation	
EMV	IEC 60601-1-2
Schutzklasse nach IEC 60601-1	I
Typ des Anwendungsteils nach IEC 60601-1	CF
Normenkonformität	IEC 60601-1: 2005+A1:2012, IEC 60601-1-2: 2007, IEC 60601-2-2: 2009, ISO 14971: 2007, ISO 13485: 2003 + Cor.1 2009
Klassifizierung nach Anhang IX der EG-Richtlinie 93/42/EWG	IIb
Dieses Medizinprodukt ist nach der Medizinprodukte-Richtlinie (MDD) 93/42/EWG mit CE-Kennzeichen versehen.	CE 0123

i Die dem CE-Kennzeichen nachgestellte Kennnummer weist die zuständige Benannte Stelle aus.

9. Saugumo klasé CF.

10 Technical data

**10.1 Technical data for
AUTOCON® III 400**

Insulation type / Classification	
EMC	IEC 60601-1-2
Protection class acc. to IEC 60601-1	I
Applied part type according to IEC 60601-1	CF
Standard compliance	IEC 60601-1: 2005+A1:2012, IEC 60601-1-2: 2007, IEC 60601-2-2: 2009, ISO 14971: 2007, ISO 13485: 2003 + Cor.1 2009
Classification according to Annex IX of the EC Directive 93/42/EEC	IIb
This medical device bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.	CE 0123

i The code number after the CE mark indicates the responsible notified body.

10 Datos técnicos

**10.1 Datos técnicos de
AUTOCON® III 400**

Tipo de aislamiento/clasificación	
CEM	CEI 60601-1-2
Clase de protección según CEI 60601-1	I
Tipo de pieza de aplicación según CEI 60601-1	CF
Conformidad con las normas	CEI 60601-1: 2005+A1:2012, CEI 60601-1-2: 2007, CEI 60601-2-2: 2009, ISO 14971: 2007, ISO 13485: 2003 + Corr.1 2009
Clasificación según el Anexo IX de la Directiva Europea 93/42/CEE	IIb
Este producto médico está provisto del símbolo CE según la Medical Device Directive (MDD) 93/42/CEE.	CE 0123

i El número de identificación pospuesto al símbolo CE designa el organismo notificado competente.

Technische Daten
Technical data
Datos técnicos

Netzeingang	220 – 240 V (UH 400/ UH 401)	100 – 127 V (UH 400U/ UH 401U)
Min. Leistungs- aufnahme	3 W / 40 VA	3 W / 40 VA
Min. Stromaufnahme	200 mA	400 mA
Max. Leistungs- aufnahme (bei 400 W)	700 W / 1150 VA	700 W / 1150 VA
Max. Strom- aufnahme (bei 400 W)	5 A	10 A @100 V 8 A @127 V
Netzsicherung (nur durch autorisiertes Servicepersonal zu wechseln)	2 x 5 AH träge, 250 V	2 x 10 AH träge, 250 V
Eingangsspannungsbereich	198 V bis 264 V	90 V bis 139,7 V
Netzfrequenz	50/60 Hz	50/60 Hz
Anschluss für Potentialausgleich	✓	✓

Power input	220 – 240 V (UH 400/ UH 401)	100 – 127 V (UH 400U/ UH 401U)
Min. power consumption	3 W / 40 VA	3 W / 40 VA
Min. current consumption	200 mA	400 mA
Max. power consumption (at 400 W)	700 W / 1150 VA	700 W / 1150 VA
Max. power consumption (at 400 W)	5 A	10 A @100 V 8 A @127 V
Line fuse (to be changed only by authorized service personnel)	2 x 5 AH slow-blow, 250 V	2 x 10 AH slow-blow, 250 V
Input voltage range	198 V to 264 V	90 V to 139.7 V
Power frequency	50/60 Hz	50/60 Hz
Connection for potential equalization	✓	✓

Entrada de corriente	220 – 240 V (UH 400/ UH 401)	100 – 127 V (UH 400U/ UH 401U)
Consumo de potencia mín.	3 W / 40 VA	3 W / 40 VA
Consumo de corriente mín.	200 mA	400 mA
Potencia consumi- da máx. (a 400 W)	700 W / 1150 VA	700 W / 1150 VA
Consumo de corriente máx. (a 400 W)	5 A	10 A @100 V 8 A @127 V
Fusible (el recambio debe ser llevado a cabo exclusiva- mente por personal de servicio técnico autorizado)	2 x 5 AH lento, 250 V	2 x 10 AH lento, 250 V
Margen de tensión de entrada	198 V hasta 264 V	90 V hasta 139,7 V
Frecuencia de red	50/60 Hz	50/60 Hz
Conexión equipotencial	✓	✓

Abmessungen und Gewicht	
Produktabmessungen (HxBxT)	177 x 447 x 457 mm
Nettogewicht	12,5 kg
Verpackungsangaben/ -abmessungen Karton (HxBxT)	498 x 530 x 650 mm
Bruttogewicht	18,2 kg

Dimensions and weight	
Device dimensions (HxWxD)	177 x 447 x 457 mm
Net weight	12.5 kg
Packaging information/ dimensions (HxWxD)	498 x 530 x 650 mm
Gross weight	18.2 kg

Dimensiones y peso	
Dimensiones del producto (al x an x pr)	177 x 447 x 457 mm
Peso neto	12,5 kg
Indicaciones/dimensio- nes del embalaje caja de cartón (al x an x pr)	498 x 530 x 650 mm
Peso bruto	18,2 kg

5. Galimybė išsaugoti
prietaiso atmintyje 300
procedūrų;

Programme	
Anzahl der Programmplätze	300
Vorgegebene Fixprogramme	Ja
Individuell programmierbar	Ja
Anzeige von Informationen auf dem Display	Ja

Programs	
Number of programs in the device	300
Default programs, factory set	Yes
Individually programmable	Yes
Information shown on the display	Yes

Programas	
Número de programas	300
Programas fijos predefinidos	Sí
Programable individualmente	Sí
Indicación de información en pantalla	Sí

6. Pasyvaus paciento elektrodo kontakto kontrolės sistema;

Überwachung der Neutralelektrode	
EASY: Electrode Application System	Ja
Anzeige einteilige, geteilte und Baby-Elektrode	Hauptmenü und Neutral-elektrodenauswahl
Anzeige des Übergangswiderstandes zwischen den Teilflächen von geteilten Neutral-elektroden im Display	Mittels Farb- und Kontaktindikator
Anzeige des Leitungswiderstandes bei Verwendung einteiliger Neutralelektroden im Display	Ja
Max. zulässiger Widerstand zwischen den Teilflächen geteilter Elektroden	300 Ω
Warnsignal bei Gefährdung in Verbindung mit Neutralelektroden	optisch, akustisch
Töne	Warnton, Aktivierungstöne, Tastenton, Startmelodie
Warnanzeige als Text im Display	Textmeldung mit weiterführenden Informationen

Neutral electrode monitoring	
EASY: Electrode Application System	Yes
Display of one-piece or split or Baby electrode	Main menu and neutral electrode selection
Contact resistance between individual sections of split neutral electrodes shown on display	Using color and contact indicator
Lead resistance shown on the display when a non-split neutral electrode is used	Yes
Maximum permissible resistance between the sections of a split electrode	300 Ω
Warning signal for hazardous conditions in connection with neutral electrodes	Visual, acoustic
Tones	Warning, activation and button tones, start melody
Warning message on the display	Text message with further information

Control del electrodo neutro	
EASY: Electrode Application System	Sí
Indicación electrodo de una pieza, de dos piezas y Baby	Menú principal y selección de electrodo neutro
Indicación en pantalla de la resistencia de paso entre las superficies parciales de los electrodos neutros de dos piezas	mediante indicador cromático y de contacto
Indicación en pantalla de la resistencia de conexión al utilizar electrodos neutros de una pieza	Sí
Resistencia máx. permitida entre las superficies parciales de los electrodos neutros de dos piezas	300 Ω
Señal de advertencia en caso de peligro en relación con electrodos neutros	visual, acústica
Tonos	Tono de advertencia, tonos de activación, tono de teclas, melodía de inicio
Indicación de advertencia en forma de texto en pantalla	Mensaje de texto con información complementaria

Sicherheitseinrichtungen	
ISSys: Integriertes Sicherheits-System	Ja
Lichtbogenregelung	ARC CONTROL
Permanente Überwachung der HF-Leckströme und Fehlermeldung	Textmeldung mit weiterführenden Informationen
Überwachung der Dosierung, Fehlermeldung im Display	Ja
Permanenter Selbsttest	Ja
Permanente Statusanzeige im Display	Ja
Anzeige von Bedienfehlern im Display	Textmeldung mit weiterführenden Informationen
Anzeige von Systemfehlern im Display	Textmeldung mit weiterführenden Informationen
Sicherheitstechnische Kontrolle (STK)	Automatische Erinnerungsfunktion (optional)
Gebrauchsanweisung	Papierform

4. Instaliuota galios savireguliacijos funkcija (priklausomai nuo pjaunamo audinio varžos);

Safety features	
ISSys (Integrated Safety System)	Yes
Arc control	ARC CONTROL
Continuous monitoring of HF leakage current and error message	Text message with further information
Dosage monitoring with error message on the display	Yes
Continuous self-test	Yes
Continuous status indication on the display	Yes
Operating errors shown on the display	Text message with further information
System errors shown on the display	Text message with further information
Safety inspection	Automatic reminder function (optional)
Instruction manual	Hard copy

Dispositivos de seguridad	
ISSys: Sistema Integrado de Seguridad	Sí
Regulación del arco voltaico	ARC CONTROL
Monitorización permanente de las corrientes de fuga de AF y mensaje de error	Mensaje de texto con información complementaria
Supervisión de la dosificación, mensaje de error en pantalla	Sí
Test automático permanente	Sí
Indicación permanente del estado en pantalla	Sí
Indicación de errores de manejo en pantalla	Mensaje de texto con información complementaria
Indicación de errores de sistema en pantalla	Mensaje de texto con información complementaria
Control técnico de seguridad (CTS)	Función automática de recordatorio (opcional)
Manual de instrucciones	Formato papel

Technische Daten

Technical data

Datos técnicos

Kühlung	
Konvektion	Ja
Lüfter temperaturgesteuert	Ja

Cooling	
Convection	Yes
Temperature-controlled fan	Yes

Refrigeración	
Convección	Sí
Ventilador con control de temperatura	Sí

Betriebsart	
Betriebsart	Intermittierend 10/30 Sek. (an/aus)

Operating mode	
Operating mode	Intermittent 10 s/30 s (on/off)

Modo de servicio	
Modo de servicio	Intermitente 10/30 s. (con./desc.)

Kenndaten	
Max. Monopolar-Leistung	400 W (an 200 Ω)
Max. Bipolar-Leistung	400 W (an 75 Ω)
Ausgangsfrequenz	350 kHz / 1 MHz
Unipolar Buchsen	2x (Fußschaltung und Fingerschaltung)
Bipolar Buchsen	3x (Fußschaltung und Fingerschaltung)
Anschluss für Fußschalter	2x
AUTOSTART	Ja
Optionen	BiVascularSafe (UH 401 und UH 401U)
Lieferumfang (siehe Kapitel 3.3)	Prüfprotokoll

Specifications	
Max. monopolar power	400 W (at 200 Ω)
Max. bipolar power	400 W (at 75 Ω)
Output frequency	350 kHz / 1 MHz
Unipolar sockets	2x (footswitch and fingerswitch)
Bipolar sockets	3x (footswitch and fingerswitch)
Connection for footswitch	2x
AUTOSTART	Yes
Options	BiVascularSafe (UH 401 and UH 401U)
Scope of supply (see section 3.3)	Inspection protocol

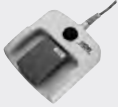


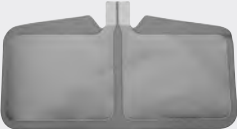


Datos característicos	
Potencia máx. monopolar	400 W (a 200 Ω)
Potencia máx. bipolar	400 W (a 75 Ω)
Frecuencia de salida	350 kHz / 1 MHz
Conectores unipolares	2 (interruptores de pedal y de dedo)
Conectores bipolares	3 (interruptores de pedal y de dedo)
Conexión para interruptor de pedal	2
AUTOSTART	Sí
Opciones	BiVascularSafe (UH 401 y UH 401U)
Volumen de suministro (véase el capítulo 3.3)	Protocolo de comprobación

7. Galimybė prijungti 2 monopolinius instrumentus vienu metu;

8. Galimybė prijungti du valdymo pedalus vienu metu;

Optional Accessories
for AUTOCON® III 400 High-End and AUTOCON® III 300

For use with AUTOCON® III 300 and AUTOCON® III 400

	UF 901	One-Pedal HF Footswitch , with button for switchover function, for use with HF generators
	UF 902	Two-Pedal HF Footswitch , with button for switchover function, for use with HF generators
	27806 US	Neutral Electrode Connecting Cable , for use with Neutral Electrode 27802
	27802	Neutral Electrode , contact surface divided into two, A=169 cm ² , for single use, package of 50, for use with AUTOCON® 50/200/350, AUTOCON® II 400 all versions, AUTOCON® III 400 and AUTOCON® III 300, Connecting Cable 27806 US required
	26 5200 43	Electrode Handle , with 2 buttons for activating the unipolar generator, yellow button: unipolar cutting, blue button: unipolar coagulation, Connecting Cable 26 5200 45 required
	26 5200 45	High Frequency Cable , for Electrode Handle 26 5200 43, length 400 cm, for use with AUTOCON® III 400 and AUTOCON® III 300

1. Kojinis jungiklis dviejų pedaly – 1 vnt.;

2. Paciento pasyvaus elektrodo laidas – 1 vnt.



PRODUCT LAUNCH

HX CAMERA HEAD

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for internal
use only!



Data sheet for HX camera heads

- Resolution: FULL HD 1. „Full HD“ aukštos raiškos standartas;
- Scanning method: Progressive scan
- Image format: 16:9
- Focal length: 16 mm 5. Židinio nuotolis (angl. focal length) 16 mm.
- Dimensions: (l x w x h): 100 mm x 36 mm x 35 mm
- Weight: TH 110 and TH 112: 130 g 4. Svoris 130 g;
TH 111 and TH 113: 142 g
- CDS:
 - o Manual wipe disinfection
 - o Sterilization:
 - Ethylene oxide (EtO) 100%
 - ASP Sterrad®: 100S ("long" + "short" cycle), NX ("Standard"), 100NX ("Standard" + "DUO" cycle)
 - Steris® AMSCO: V-PRO 1, V-PRO 1 Plus, V-PRO maX
 - Steris®: SYSTEM 1E (US only), SYSTEM 1 (outside US)
 - o High-level disinfection: Cidex 14-Day, Resert XL HLD

- No SPIES™ technologies for standard version

	WL	CLARA	CHROMA	SPECTRA	AF	PDD
HX	•					
HX-P	•					
HX FI	•		•	•	•	•
HX-P FI	•		•	•	•	•

- Digital zoom 3. Skaitmeninis priartinimas
- CF defib safety rating
- Ergonomic design
- Freely programmable camera head buttons

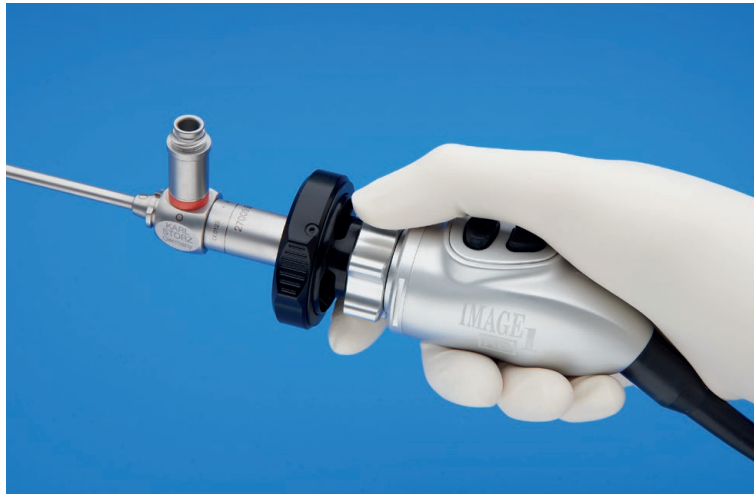
PRODUCT LAUNCH

HX CAMERA HEAD

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3. Advantages at a glance



Ergonomics:

User-friendliness and ergonomics were key considerations in the development of the HX series. Its size and weight have been significantly reduced when compared with the 3-chip series. Ergonomics are achieved by reducing size and weight but also by adapting form and function to user needs. We kept the proven control system via three camera head buttons. The focus ring is optimally adapted to the anatomy of the hand and is easy to reach.

Haptics was another important development aspect. A high-quality metal casing conveys quality, robustness, and longevity.

3. (vaizdo fokusavimo
žiedas)

PRODUCT LAUNCH

HX CAMERA HEAD

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use only!*



5. Product positioning

HX CAMERA HEAD (ONE-CHIP)	H3 SPIES™ CAMERA HEAD (THREE-CHIP, ZOOM)
Much smaller and more lightweight than the three-chip camera heads HX and HX FI (130 g), HX-P and HX-P FI (142 g)	H3-Z (270 g), H3-P (226 g)
One-chip system	Three-chip system
Fixed focus, digital zoom	Digital zoom and optical parfocal zoom (no optical zoom in pendulum version)
HX and HX-P: no SPIES™ technologies available	All SPIES™ technologies available
	H3-Z FI ICG-compatible
Future HX-FI camera heads AF/PDD-compatible	
EtO, Steris®, Sterrad®	EtO, Steris®, Sterrad®, autoclavable (for TH 104)
Can be connected to the IMAGE1 X-LINK™	Can be connected to the IMAGE1 H3-LINK™ and IMAGE 1 HUB™
Brilliant image quality in FULL HD 1920 x 1080 (progressive scan)	Brilliant image quality in FULL HD 1920 x 1080 (progressive scan)
CMOS technology	CCD technology
Lower price than H3 heads	

(The comparative advantages of the individual heads are highlighted in yellow.)

2. CMOS jutiklis;



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 18 04 84462 012

Manufacturer:

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
GERMANY

Facility(ies):

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen, GERMANY



Product

Category(ies):

- medical and surgical instruments
 - active surgical instruments
 - implantable clamps for ligation of tubings and vessels
 - bone implants (non active)
 - rigid and flexible endoscopes for diagnostics and therapy
 - active medical devices and surgical auxiliary devices
 - cameras, devices and auxiliary devices for imaging procedure with non ionizing radiation
- [for a detailed list of product groups class II a and higher we refer to the KARL STORZ internal document C2.3.1 (in the current updated version)]

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713129927

Valid from:

2018-07-17

Valid until:

2023-07-16

Date, 2018-07-03



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1



Gaminio aptarnavimas

EC sertifikatas

Visiško kokybės užtikrinimo sistema

Direktyva 93/42/EEC dėl Medicinos prietaisų (MDD), Priedas II išskyrus (4)

(Prietaisų klasės IIa, IIb arba III)

Nr.G1 18 04 84462 012

Gamintojas

KARL STORZ SE& Co, KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Vokietija

Gamykla(os)

KARL STORZ SE& Co, KG
Dr.-Karl-Storz-Straße 34,
78532 Tuttlingen
Vokietija



Gaminio kategorija(jos)

- medicininiai ir chirurginiai instrumentai;
- aktyvūs chirurginiai instrumentai;
- implantuojami fiksatoriai vamzdelių ir kraujagyslių ligavimui;
- kaulų implantai (neaktyvus);
- diagnostikai ir gydymui skirti standieji ir lankstieji endoskopai;
- aktyvūs medicinos prietaisai bei pagalbinių chirurginių prietaisai;
- kameros, prietaisai bei pagalbinių prietaisai vaizdavimo procedūroms be jonizuojančios spinduliuotės atlikti [detalų IIa ir aukštesnės klasės gaminių grupių sąrašą galima rasti vidiniame kompanijos KARL STORZ C2.3.1 dokumente (dabartinėje atnaujintoje dokumento versijoje)]

Sertifikavimo įstaiga „TÜV SÜD Product Service GmbH“ pareiškia, kad aukščiau minėtas gamintojas įdiegė atitinkamų prietaisų/prietaisų kategorijų projektavimo, gamybos bei galutinio patikrinimo kokybės užtikrinimo sistemą pagal II priedą MDD. Ši kokybės užtikrinimo sistema atitinka šitos Direktyvos reikalavimus ir turi būti periodiškai tikrinama. Klasės III prietaisų realizavimui būtinas II (4) priedo sertifikatas. Žr. pastabas kitoje lapo pusėje.

Ataskaitos Nr.: 713129927

Galioja nuo: 2018-07-17
Galioja iki: 2023-07-16

Data 2018-07-03 /Parašas/

[Redacted signature]

„TÜV SÜD Product Service GmbH“ yra notifikuotoji įstaiga, identifikacijos Nr. 0123

[Redacted signature]





Product Service

**Mehr Wert.
Mehr Vertrauen.**

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

Your Ref/Name	Our Ref/Name	Tel. /E-Mail	Fax	Date	Page
84462_2023_06_MDD	713300646-1	+49 89 50084-652	n.a.	28. June 2023	1 von 66
	ID 2023-236	marie-astrid.viard@tuvsud.com			

Notified Body Confirmation Letter

Reference: 713300646-1

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen
Germany

SRN Number: DE-MF-000005723

Sitz: München
Handelsregister München HRB 85742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
UST-IdNr. DE129484267
Informationen gemäß § 2 Abs. 1 DL-InfoV
unter www.tuvsud.com/impressum

Aufsichtsrat:
Holger Lindner (Vorsitzender)
Geschäftsführung:
Walter Reithmaier (Sprecher)
Patrick van Welij

Telefon: +49 89 50084-747
www.tuvsud.com/ps

TUV®

TÜV SÜD Product Service GmbH
Niederlassung München

Ridlerstraße 65
80339 München
Deutschland



Product Service

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

- Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur:

E-Mail:

Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signatur:

E-Mail:

Head of Certification Body - Deputy



ATTACHMENT

Table 1: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Accessories for Insufflators	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Active controlling systems, components of software (SCB)	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #1; CA# Evidence #2; CA#
EM Navigation	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Foot Switch for Laser	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Foot Switches for Motor Control Unit	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Foot Switches for Pumps	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Instruments with movable jaws	<input type="checkbox"/> N/A or	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Instruments without movable jaws/ HF Electrodes	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Suction/ Irrigation Instruments	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Generators	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Foot Switches	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
HF Working Elements / working inserts	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Insufflators	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Laser Devices	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Lithotripsy Probes	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Suction/ Irrigation Pumps	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tubing Sets Insufflators	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input checked="" type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cannulas	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Instruments with movable jaws	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Instruments without movable jaws	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
ENT Balloon Catheter	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fiberscopes with channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fiberscopes without channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Flexible Videoscopes with channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Flexible Videoscopes without channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



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	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Laser Fibers	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Light Carrier (adaptable)	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



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	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Light Sources	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Handpieces/ Motors	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



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	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Morcellator blades	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Morcellator handpieces	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Motor Control Unit	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optics (Telescopes) with channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



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	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optics (Telescopes) without channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
Rigid Videoscopes with channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class III implantable custom-made device		
Rigid Videoscopes without channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
Semiflexible endoscopes with channel	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Shaver/ Drills	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sheaths	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Suction/ Irrigation Instruments	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocars	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Working Elements/ Working Inserts	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G1 084462 0012 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Adhesive bandage	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers for Touchscreen	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Covers for camera	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical plume evacuation system filter	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide probes	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical irrigation/aspiration tubing sets	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgical irrigation/aspiration handles	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Optic stoppers	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Spray catheters	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocar valves	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Valve seals	<input type="checkbox"/> N/A or <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Certification as follows: Certificate #: G2S 084462 0013 Rev.01; NB # 0123 or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which the TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Adenotom	<input type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Applicator	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Artery clamp	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Barrel catcher	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Biopsy forceps	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> N/A



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Biopsy scoop	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Blades	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bone file	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bone shrapnel	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Bougie-Urethrotom	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Brushes	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cement applicator	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Chisel	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Clamps	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Conchotom	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Curette	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilatation mandrel	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilation sets	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives
Dilation sleeve	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dilators	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> N/A



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	or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Dissectors	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Elevator	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows:



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	<input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Endotom	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Extractor	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #:



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	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Fixation instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Footplate hooks	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or



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	<input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Forceps	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Gripper	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



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	<input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide probes	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide sleeves	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or



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	<input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Guide wire	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Hollow milling cutter	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Hooks	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Injection cannula	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Insert Femoral Targeting Device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Knives	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Lock cap	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> N/A



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Mandrel	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Measuring cylinder	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Micro fork	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Needle	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Needle holder	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Obturator	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Osteotome	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Outer cannula	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Outer sheath	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Patellar sawing template	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Perforator	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Plunger	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Probe	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Punching instruments	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Puncture needle	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Pylorotome	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Raspatorium	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> N/A



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	or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Rasp	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Retactor	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or



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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Saw	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Scalpel handle	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #:



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	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Scissors	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Screw driver	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Seaming instrument	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Self-retaining retractor	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives



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	<input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Sleeves	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Speculum	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Spoon	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tampon thongs	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tap	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Tendon strength tester	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			Evidence #2; CA#
Thread clamps	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread guide	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread hook	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input type="checkbox"/> N/A



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	or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread scissors	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Thread forceps	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> N/A or	<input type="checkbox"/> N/A or



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	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trepan	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Trocar	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #:



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	<input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Valves	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or <input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Work inserts	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable non-WET device <input type="checkbox"/> Class IIb excluding Class IIb implantable non-WET <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD:	<input type="checkbox"/> N/A or <input type="checkbox"/> Certification as follows: Certificate #1; NB #: Certificate #2; NB #: or



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	<input type="checkbox"/> Class I devices placed on the market in sterile condition <input type="checkbox"/> Class I devices with a measuring function <input checked="" type="checkbox"/> Class I devices that qualify as re-usable surgical instruments <input type="checkbox"/> Class III implantable custom-made device		<input checked="" type="checkbox"/> N/A - Device did not require a Notified Body certificate under Directives or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Product Service

Confirmation Letter Version History

Date	NB internal reference traceable to each version of the letter	Action
2023-06-27	713300646-1	Initial letter
2023-06-28	713300646-1	Correction of certificate for class Is devices

Number ²

E_GMZ_27HK510S_DOC_202412010001

Name and address of the Manufacturer ³

LG Electronics Inc.
168, Suchul-daero, Gumi-si, Gyeongsangbuk-do,
39368 Republic of Korea

(Head Office)
LG Electronics Inc.
LG Twin Towers 128 Yeoui-daero, Yeongdeungpo-gu, Seoul, 07336, Korea

This declaration of conformity is issued under the sole responsibility of the manufacturer ⁴

Object of the declaration ⁵

Product information ⁶	Product Name	Model Name
	Medical Monitor	27HK510S (Type Name: 27HK510S-W)
Additional information ⁷ <div>EMDN code: Z11900802 Adaptor: DA-120D19 Serial Number: YMMKCXXXXXXX (Y:year, MM:month, KC:manufacturing site, XXXXXXXX:random) SRN: (Manufacturer) KR-MF-000001897 (Authorized Representative) DE-AR-000044729 Basic UDI-DI: 8806098MONITOR-SURGICAL62</div>		

The device that is covered by the present declaration is in conformity with this regulation and any other relevant Union legislation that provides for the issuing of an EU declaration of conformity: ⁸

- References to the relevant harmonized standards used or references to the technical specifications in relation to which conformity is declared ⁹

Medical Device Regulation 2017/745

CLASSIFICATION: Class I by Rule 13 of Annex VIII, Medical Device Regulation 2017/745
CONFORMITY ASSESSMENT ROUTE: Performed according to Annex II, Annex III, Annex IV and Annex V, Medical Device Regulation 2017/745

EN ISO 13485:2016/A11:2021	EN 60601-1-2:2015/A1:2021	EN 60601-1:2006/A2:2021
EN ISO 14971:2019/A11:2021		EN 62304:2006/A1:2015
ISO/TR 24971:2020		EN 62366-1:2015/A1:2020
ISO/TR 20416:2020		EN 60601-1-6:2010/A2:2021
EN ISO 15223-1:2021		
EN ISO 20417:2021		

RoHS Directive 2011/65/EU

DIN EN IEC 63000:2019-05

Intended Purpose

This Medical Monitor is intended to provide color video displays and images from medical equipment which include laparoscope and endoscopy systems for surgery and various medical imaging systems.

The notified body ¹⁰

N/A

and issued the certificate

N/A

performed

N/A

Additional information ⁷

Factory Information:
LG Electronics Inc.
168, Suchul-daero, Gumi-si, Gyeongsangbuk-do, 39368 Republic of Korea
LG Electronics Nanjing New Technology Co., Ltd.
NO.346, Yaoxin Road, Economic & Technical Development Zone, Nanjing, 210038 China
EU Authorized Representative: LG Electronics Deutschland GmbH, Alfred-Herrhausen-Allee 3-5, 65760 Eschborn, Germany

Signed for and on behalf of: ¹¹ LG Electronics Inc.

Place and Date of issue:
168, Suchul-daero, Gumi-si, Gyeongsangbuk-do,
39368 Republic of Korea
01. December. 2024

Name and Surname / Function:

- 1 (EN) EU Declaration of Conformity (BG) ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ С ИЗИСКВАНИЯТА НА ЕС (ES) Declaración UE de Conformidad (CS) EU Prohlášení o shodě (DA) EU Overensstemmelseserklæring (DE) EU-Konformitätserklärung (ET) ELI Vastavuseklaratsioon (EL) ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ (FR) Déclaration UE de Conformité (GA) Dearbhí Comhréireachta an AE (IT) Dichiarazione UE di Conformità (LV) ES Atbilstības Deklarācija (LT) ES Atitikties Deklaracija (HU) EU-Megfelelőségi Nyilatkozat (MT) Dikjarazzjoni Tal-Konformità Tal-UE (NL) EU Conformiteitsverklaring (PL) Deklaracja Zgodności UE (PT) Declaração de Conformidade UE (RO) Declarația de Conformitate UE (SK) Vyhlásenie o Zhode EÚ (SL) Izjava EU o Skladnosti (FI) EU-Vaatimustenmukaisuusvakuutus (SV) EU-Försäkran om Överensstämmelse (TR) Uygunluk Beyanı (NO) EU Samsvarserklæring (HR) EU-ova Izjava o skladnosti (IS) ESB Samræmisfyrirlysing**
- 2 (EN) Number (BG) № (ES) Nº (CS) Č. (DA) Nr. (DE) Nr./ (ET) Nr./ (EL) Αριθ. (FR) N°/ (GA) Uimhir (IT) N./ (LV) Nr./ (LT) Nr. (HU) Szám/ (MT) Numru (NL) Nr. (PL) Nr. (PT) N.º (RO) Nr./ (SK) Číslo/ (SL) Št./ (FI) N:o (SV) Nr./ (TR) Sayısı (NO) Nr. (HR) Broj (IS) Númer**
- 3 (EN) Name and address of the Manufacturer (BG) Наименование и адрес на производителя (ES) Nombre y dirección del fabricante (CS) Obchodní jméno a adresa výrobce (DA) Fabrikantens navn og adresse (DE) Name und Anschrift des Herstellers (ET) Valmistaja nimi ja aadress (EL) Όνομα και διεύθυνση κατασκευαστή (FR) Nom et adresse du fabricant (GA) Ainm agus seoladh an Mhóraróra (IT) Nome e indirizzo del fabbricante (LV) Ražotāja nosaukums un adrese (LT) Gamintojo pavadinimas ir adresas (HU) Gyártó neve és címe (MT) Isem u indirizz tal-manifattur (NL) Naam en adres van de fabrikant (PL) Nazwa i adres producenta (PT) Nome e endereço do fabricante (RO) Numele și adresa Producătorului (SK) Obchodné meno a adresa výrobcu (SL) Ime in naslov proizvajalca (FI) Valmistajan nimi ja osoite (SV) Tillverkarens namn och adress (TR) İmalatçının adı ve adresi (NO) Navn på og adresse til produsenten (HR) Naziv i adresa proizvođača (IS) Nafn og heimilisfang framleiðanda**
- 4 (EN) This declaration of conformity is issued under the sole responsibility of the manufacturer (BG) За настоящата декларация за съответствие отговорност носи единствено производителят (ES) La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante (CS) Toto prohlášení o shodě vydal na vlastní odpovědnost výrobce (DA) Denne overensstemmelseserklæring udstedes på fabrikantens ansvar (DE) Diese Konformitätserklärung wird unter der alleinigen Verantwortung des Herstellers abgegeben (ET) Käesolev vastavuseklaratsioon on välja antud valmistaja ainuvastutuseel (EL) Η παρούσα δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή (FR) La présente déclaration de conformité est établie sous la seule responsabilité du fabricant (GA) Eisítear an dearbhí comhréireachta faoi fheargracht aonair an mhóraróra (IT) La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del fabbricante (LV) Šī atbilstības deklarācija ir izdota vienīgi uz šāda ražotāja atbildību (LT) Ši atitikties deklaracija išduota tik gamintojo atsakomybe (HU) E megfelelőségi nyilatkozat a gyártó kizárólagos felelősségére kerül kibocsátásra (MT) Din id-dikjarazzjoni tal-konformità tinhareg taht ir-responsabbiltà unika tal-manifattur (NL) Deze conformiteitsverklaring wordt verstrekt onder volledige verantwoordelijkheid van de fabrikant (PL) Niniejsza deklaracja zgodności wydana zostaje na wyłączną odpowiedzialność producenta (PT) A presente declaração de conformidade é emitida sob a exclusiva responsabilidade do fabricante (RO) Prezenta declarație de conformitate este emisă pe răspundere exclusivă a producătorului (SK) Toto vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť výrobcu (SL) Ta izjava o skladnosti se izda na lastno odgovornost proizvajalca (FI) Tämä vaatimustenmukaisuusvakuutus on annettu valmistajan yksinomaista vastuulla (SV) Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar (TR) Bu uygunluk beyanı, imalatçının sorumluluğu altında verilir (NO) Denne samsvarserklæringen er utstedt på produsentens eneansvar (HR) Za izdavanje ove izjave o skladnosti isključivo je odgovoran proizvođač (IS) Þessi samræmisfyrirlysing er gefin út eingöngu á ábyrgð framleiðanda**
- 5 (EN) Object of the declaration (BG) Обект на декларацията (ES) Objeto de la declaración (CS) Předmět prohlášení (DA) Erklæringens genstand (DE) Gegenstand der Erklärung (ET) Deklareeritava ese (EL) Σκοπός της δήλωσης (FR) Objet de la déclaration (GA) Cuspóir an dearbhaithe (IT) Oggetto della dichiarazione (LV) Deklarācijas priekšmets (LT) Deklaracijos objektas (HU) A nyilatkozat tárgya (MT) L-għan tad-dikjarazzjoni (NL) Voorwerp van de verklaring (PL) Przedmiot deklaracji (PT) Objecto da declaração (RO) Obiectul declarației (SK) Predmet vyhlásenia (SL) Predmet izjave (FI) Vakuutuksen kohde (SV) Föremål för försäkran (TR) Beyanın nesne (NO) Erklæringens gjenstand (HR) Predmet izjave (IS) Hlutur til yfirlýsingar**
- 6 (EN) Product information; Product Name; Model Name (BG) Информация за продукта, името на продукта, името на модела (ES) Información del producto; nombre del producto; nombre del modelo (CS) Informace o výrobku; Název výrobku; Název modelu (DA) Produkt information; Produktnavn; Modelnavn (DE) Produktinformation; Produktname; Modellname (ET) Toote kirjeldus; Toote nimetus; Mudeli nimi (EL) Πληροφορίες για το προϊόν, όνομα προϊόντος, όνομα μοντέλου (FR) Information sur le produit; Nom du produit; Nom du modèle (GA) Faisnéis Táirge; Ainm Táirge; Ainm Múnla (IT) Informazioni sul prodotto; denominazione del prodotto; Nome del modello (LV) Informācija par izstrādājumu; Izstrādājuma nosaukums; Modeļa nosaukums (LT) Informacija apie produktą; produkto pavadinimas; modelio pavadinimas (HU) Termékinformáció; a termék neve; típusnév (MT) Informazzjoni tal-prodott; isem tal-prodott; isem tal-modelli (NL) Product informatie, Product naam; Model naam (PL) Informacje o produkcie; nazwa produktu; nazwa modelu (PT) Informação sobre o produto; Nome do Produto; Designação do Modelo (RO) Informații despre Produs; Denumire Produs; Nume Model (SK) Informácie o výrobku; Názov výrobku; Názov modelu (SL) Podatki o izdelku; ime izdelka; ime modela (FI) Tuotetiedot; tuotteen nimi; malli nimi (SV) Produktinformation; produktnamn; modellnamn (TR) Ürün bilgileri; Ürün Adı; Model Adı (NO) Produktinformasjon, Produktnavn, Modellnavn (HR) Podaci o proizvodu; Naziv proizvoda; Naziv modela (IS) Vörupplýsingar; Nafn vöru; Nafn gerðar**
- 7 (EN) Additional information (BG) Допълнителна информация (ES) Información adicional (CS) Další informace (DA) Supplerende oplysninger (DE) Zusätzliche Angaben (ET) Lisateave (EL) Συμπληρωματικές πληροφορίες (FR) Informations supplémentaires (GA) Faisnéis bhreise (IT) Ulteriori informazioni (LV) Papildu informācija (LT) Papildoma informacija (HU) Kiegészítő információk (MT) Informazzjoni addizzjonali (NL) Aanvullende informatie (PL) Informacje dodatkowe (PT) Informações complementares (RO) Informații suplimentare (SK) Dodatočné informácie (SL) Dodatni podatki (FI) Lisätietoja (SV) Ytterligare information (TR) Ek bilgi (NO) Tilleggsopplysninger (HR) Dodatne informacije (IS) Viðbótarupplýsingar**
- 8 (EN) The object of the declaration described above is in conformity with the relevant Community harmonisation legislations (BG) Предметът на декларацията, описан по-горе, отговаря на съответното законодателство на Общността за хармонизация (ES) El objeto de la declaración descrita anteriormente es conforme a la legislación comunitaria de armonización pertinente (CS) Vše relevantní předmět prohlášení je ve shodě s harmonizačními právními předpisy Společenství (DA) Gjenstanden for erklæringen, som beskrevet ovenfor, er i overensstemmelse med den pågældende EF-harmoniseringslovgivning (DE) Der oben beschriebene Gegenstand der Erklärung erfüllt die einschlägigen Harmonisierungsrechtsvorschriften der Gemeinschaft (ET) Õlakirjeldatud deklaratsioon toode on kooskõlas asjaomaste ühenduse ühtlustatud õigusaktidega (EL) Ο στόχος της δήλωσης που περιγράφεται παραπάνω είναι σύμφωνα προς τη σχετική κοινοτική νομοθεσία εναρμόνισης (FR) L'objet de la déclaration décrit ci-dessus est conforme à la législation communautaire d'harmonisation applicable (GA) Tá cuspóir an dearbhaithe a thuairiscítear thuas i gcomhréir le reachtaíocht ábhartha um chomhchuibhiú de chuid an Chomhphobail (IT) L'oggetto della dichiarazione di cui sopra è conforme alla pertinente normativa comunitaria di armonizzazione (LV) Iepriekš aprakstītais deklarācijas priekšmets atbilst attiecīgajam Kopienas saskaņotajam tiesību aktam (LT) Pirminiu aprašytas deklaracijos objektas atitinka susijusius derinamuosius Bendrijos teisės aktus (HU) A fent ismertetett nyilatkozat tárgya megfelel a vonatkozó közösségi harmonizációs jogszabálynak (MT) L-għan tad-dikjarazzjoni deskritt hawn fuq huwa konformi mal-legiżlazzjoni ta' armonizzazzjoni rilevanti tal-Komunità (NL) Het hierboven beschreven voorwerp is conform de desbetreffende communautaire harmonisatiewetgeving (PL) Wymieniony powyżej przedmiot niniejszej deklaracji jest zgodny z odpowiednimi wymaganiami wspólnotowych przepisów harmonizacyjnych (PT) O objecto da declaração acima mencionada está em conformidade com a legislação comunitária aplicável em matéria de harmonização (RO) Obiectul declarației descris mai sus este în conformitate cu legislația comunitară relevantă de armonizare (SK) Uvedený predmet vyhlásenia je v súlade s príslušnými harmonizačnými právnymi predpismi Spoločenstva (SL) Predmet navedene izjave je v skladu z ustreznimi usklajevalno zakonodajo Skupnosti (FI) Edellä kuvattu vakuutuksen kohde on asiaa koskevan yhdenmukaistamista koskevan yhteisön lainsäädännön vaatimusten mukainen (SV) Föremålet för försäkran ovan överensstämmer med den relevanta harmoniserade gemenskapslagstiftningen (TR) Yukarıda açıklanan bildirimin nesnesi ilgili Topluluk uyum mevzuatına uygundur (NO) Erklæringens gjenstand beskrevet ovenfor er i samsvar med det relevante samfunnet, og harmoniserer med lovgivningen (HR) Goro opisani predmet izjave sukladan je mjerodavnom uskladenom zakonodavstvu Zajednice (IS) Hluturinn til yfirlýsingar sem lýst er hér fyrir ofan samræmist víðeigandi samhæfingarlöggjöfum Bandalagsins**
- 9 (EN) References to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared (BG) Наименованията на използваните хармонизирани стандарти или техническите спецификации, спрямо които се декларира съответствието (ES) Referencias a las normas armonizadas pertinentes utilizadas, o referencias a las especificaciones técnicas respecto a las cuales se declara la conformidad (CS) Případně odkazy na příslušné harmonizované normy, které byly použity, nebo na technické specifikace, na jejichž základě se shoda prohlašuje (DA) Referencer til de relevante anvendte harmoniserede standarder eller referencer til de tekniske specifikationer, som der erklæres overensstemmelse med (DE) Angabe der einschlägigen harmonisierten Normen, die zugrunde gelegt wurden, oder Angabe der technischen Spezifikationen, für die die Konformität erklärt wird (ET) Viited kasutatud asjakohastele ühtlustatud standarditele või viited tehnilistele spetsifikatsioonidele, millega seoses vastavust kinnitatakse (EL) ΰνεια των σχετικών εναρμόσιμένων προτύπων που χρησιμοποιήθηκαν ή των τεχνικών προδιαγραφών με βάση τις οποίες δηλώνεται η συμμόρφωση (FR) Références des normes harmonisées pertinentes appliquées ou des spécifications techniques par rapport auxquelles la conformité est déclarée (GA) Tagairtí do na caighdeáin chomhchuibhithe ábhartha a úsáidtear nó tagairtí do na sonraíochtaí teicniúla i ndáil leis an gcomhréireacht a dhearbhaítear (IT) Riferimenti alle pertinenti norme armonizzate utilizzate o i riferimenti alle specifiche tecniche in relazione alle quali è dichiarata la conformità (LV) Norādes uz attiecīgajiem saskaņotajiem standartiem vai norādes uz tehniskām specifikācijām, attiecībā uz ko tiek deklarēta atbilstība (LT) Taikyti darniųjų standartų nuorodos arba techninių specifikacijų, pagal kurias buvo deklaruota atitiktis, nuorodos (HU) Adott esetben hivatkozás az alkalmazásra került vonatkozó harmonizált szabványokra, illetőleg azokra a műszaki leírásokra, amelyekre nézve a megfelelésről nyilatkoznak (MT) Referenzi għall-standards armonizzati rilevanti li ntużaw, jew referenzi għall-ispekkifikazzjonijiet li b'relazzjoni għalihom qed tiġi ddikjarata l-konformità (NL) Vermelding van de toegepaste geharmoniseerde normen of van de technische specificaties waarop de conformiteitsverklaring betrekking heeft (PL) Odwołania do odpowiednich norm zharmonizowanych, które zastosowano, lub do specyfikacji technicznych, w odniesieniu do których deklarowana jest zgodność (PT) Referências às normas harmonizadas aplicáveis utilizadas ou às especificações técnicas em relação às quais é declarada a conformidade (RO) Rîmîterii la standardele armonizate relevante folosite sau trîmîterii la specificațiile tehnice în legătură cu care se declară conformitatea (SK) Prípadně odkazy na příslušné použité harmonizované normy alebo odkazy na technické specifikácie, na základe ktorých sa vyhlasuje zhoda (SL) Napotila na uporabljene usklajene standarde ali napotila na tehnične specifikacije za skladnost, ki so navedene na izjavi (FI) Viitauks asiaankuuluviin yhdenmukaistettuihin standardeihin, joita on käytetty, tai viitauks tekniisiin eritelmiin, joiden perusteella vaatimustenmukaisuusvakuutus on annettu (SV) Hänvisningar till de relevanta harmoniserade standarder som använts eller hänvisningar till de tekniska specifikationer enligt vilka överensstämmelsen försäkras (TR) İlgili uyumlulaştırılmış kulanılan standartlar veya uygunluk beyanı ile ilgili olarak teknik referanslar referanslar (NO) Henvisinger til de relevante harmoniserte standardene som er brukt eller henvisinger til de spesifikasjonene det erklæres samsvar med (HR) Upućivanje na mjerodavne uskladene norme ili upućivanje na tehničke specifikacije na temelju kojih se izjavljuje skladnost (IS) Tilvísanir í víðeigandi samhæfingarlöggjöfum Bandalagsins eða tilvísanir í þær tækniforskriftir sem tengjast samræmisfyrirlysingunni**
- 10 (EN) The notified body (BG) Нотифицираният орган (ES) El organismo notificado (CS) Oznamovaný subjekt (DA) Det bemyndigede organ (DE) Die notifizierte Stelle (ET) Teavitatud asutus (EL) ο κοινοποιημένος οργανισμός (FR) L'organisme notifié (GA) Rinne an comhlachd dá dtugtar fógra (IT) l'organismo notificato (LV) Pilnvarotā iestāde (LT) Notifikuotoji įstaiga (HU) A bejelentett szervzet (MT) Il-korp notifikat (NL) De aangemelde instantie (PL) Jednostka notyfikowana (PT) o organismo notificado (RO) Organismul notificat (SK) Notifikačný orgán (SL) Je priglajeni organ (FI) Ilmoitettu laitos (SV) Det anmälda organet (TR) Kuruluşla bildirilmiş (NO) Det meldte organ (HR) Obaviješteno tijelo (IS) Hinn tilkynnt aðili**
- 11 (EN) Signed for and on behalf of (BG) Подпис за или от името на (ES) Firmado por y en nombre de (CS) Podpsáno za a jménem (DA) Underskrevet for og på vegne af (DE) Unterzeichnet für und im Namen von (ET) Kelle nimel ja poolt/alla kirjutatud (EL) Υπογραφή για λογαριασμό και εξ ονόματος (FR) Signé par et au nom de (GA) Sinithe le haghaidh agus thar ceann an (IT) Firmato in vece e per conto di (LV) Parakstīts (LT) Už ką ir kieno vardu pasirašyta (HU) Cégészér aláírás (MT) Iffirmata għal u f'isem (NL) Ondertekent voor en namens (PL) Podpisano w imieniu (PT) Assinado por e em nome de (RO) Semnat pentru și în numele (SK) Podpsané za a v mene (SL) Podpisano za in v imenu (FI) puolesta allekirjoittanut (SV) Undertecknat för (TR) Ve adına imzalanmıştır (NO) Undertegnet for og på vegne af (HR) Potpisano za i u ime (IS) Undirritað fyrir og fyrir hönd**