



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

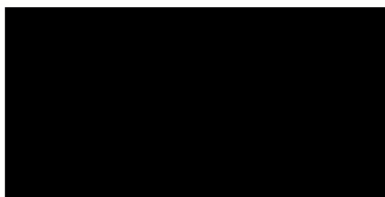
Valid from:

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

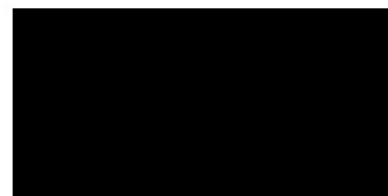
Data 2018-07-03 /Parašas/
Stefan Preiß



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

Psl. 1 iš 1

„TÜV SÜD Product Service GmbH“ * Zertifizierstelle * Ridlerstraße 65 * 80339 München * Vokietija





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
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TÜV SÜD Product Service GmbH
Niederlassung München

Ridlerstraße 65
80339 München
Deutschland

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

Signature

E-Mail: Marie-Astrid.Viard@tuvsud.com

Marie-Astrid Viard
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Signature

E-Mail: Julia.Hoyer@tuvsud.com

Julia Hoyer
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



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	<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



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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 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



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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#
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



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 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



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#
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



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#
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



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#
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



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	<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:



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	<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



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	<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



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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#
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 #:



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#
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



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#
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



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#
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



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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#
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



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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#
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



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

Numeris	Numeris	Tel. /E-Mail	Fax	data	Lapas
84462_2023_06_MDD	713300646-1	+49 89 50084-652	n.a.	28. June 2023	1 iš 66
	ID 2023-236	marie-astrid.viard@tuvsud.com			

Notifikuotosios įstaigos patvirtinimo laiško numeris:
713300646-1

Kam tai gali būti aktualu,

Oficialios paraiškos, rašytinio susitarimo ir tinkamos priežiūros statuso patvirtinimas pagal Reglamentą ES 2023/607, iš dalies keičiantį reglamentus (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatų tam tikriems medicinos prietaisams ir Vitro diagnostikos medicinos prietaisai.

Šiuo laišku patvirtinama, kad TÜV SÜD Product Service GmbH, paskelbtoji įstaiga (NB), paskirta pagal Reglamentą (ES) 2017/745 (MDR) ir pažymėta NANDO numeriu 0123, gavo oficialų prašymą pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrąją pastraipą su šiuo gamintoju.

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Dr.-Karl-Storz-Straße 34
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unter www.tuvsud.com/impressum

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

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TUV®

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Niederlassung München

Ridlerstraße 65
80339 München
Deutschl

Prietaisai, kuriems pateikta oficiali paraiška ir pirmiau minėtas rašytinis susitarimas, nurodyti toliau pateiktose lentelėse, žr.

- 1 lentelėje nurodyti įrenginiai, dėl kurių buvo gauta MDR paraiška, sudaryta rašytinė sutartis ir dėl kurių TÜV SÜD Product Service GmbH taip pat yra atsakinga už atitinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą.

- 2 lentelėje nurodyti įrenginiai, dėl kurių buvo gauta MDR paraiška ir sudaryta rašytinė sutartis, tačiau TÜV SÜD Product Service GmbH dar neprisirišė atsakomybės už tinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą.

Įrenginiams, kuriems išduoti sertifikatai, išduoti pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD), kurių galiojimas pasibaigė po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20 d., bet nebuvo atšauktas, šis laiškas taip pat patvirtina, kad:

- gamintojas pasirašė rašytinę sutartį pagal MDR iki MDD/AIMDD sertifikato galiojimo pabaigos datos; arba

- pateikė įrodymus, kad valstybės narės kompetentinga institucija suteikė leidžiančią nukrypti nuostatą pagal MDR 59 straipsnio 1 dalį, arba

- pateikė įrodymų, kad valstybės narės kompetentinga institucija pagal MDR 97 straipsnio 1 dalį suteikė išimtį nuo taikytinos atitikties vertinimo procedūros,

iki 2023 m. kovo 20 d. atitinkamiems įrenginiams.

Pereinamieji terminai, taikomi šiame laiške nurodytiems įrenginiams, jei gamintojas nuolat laikosi kitų sąlygų, nurodytų MDR 120.3c straipsnyje (su pakeitimais, padarytais ES 2023/607), nurodyti toliau:

- 2026 m. gegužės 26 d. III klasės implantuojamiems prietaisams pagal užsakymą
- 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems prietaisams, išskyrus nusistovėjusias technologijas (WET – siūlai, kabės, dantų plombos, dantų briketai, dantų vainikėliai, varžtai, pleištai, plokštelės, laidai, kaiščiai, spaustukai ir jungtys)
- 2028 m. gruodžio 31 d. – kitiems IIb klasės, IIa klasės, I klasės prietaisams, kurie pateikiami į rinką sterilūs arba turi matavimo funkciją
- 2028 m. gruodžio 31 d. prietaisams, kuriems pagal MDD nereikia dalyvauti notifikuotosios įstaigos, bet pagal MDR (pvz., I klasės prietaisams, kurie atitinka daugkartinio naudojimo chirurginių instrumentų reikalavimus)

Notifikuotosios įstaigos vardu,

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Servic