

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Manufacturer: CAIR LGL

Address:

1 Allée Des Chevreuils
Lissieu
69380
France

Single Registration Number: FR-MF-000007921

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):


Graeme Lambage, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Enteral feeding, drug administration/ Enteral suction devices and accessories	Class IIa



First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 772264 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3566773	Issued



First Issue Date: **2024-05-13**

Current Issue Date: **2024-05-13**

Starting Validity Date: **2024-05-13**

Expiry Date: **2029-05-12**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas, I ir III skyriai

MMDDRR 772264 RR000

Gamintojas: CAIR LGL

Adresas:

1 Allée Des Chevreuils

Lissieu

69380

Prancūzija

Bendras registracijos numeris: FR-MF-000007921

Žr. pridedamą prietaisų sąrašą. Remiantis mūsų kokybės sistemos patikrinimu pagal Reglamentą (ES) 2017/745, IX priedą, I ir III skyrius, kokybės sistema atitinka Reglamento reikalavimus. Norint pateikti rinkai III klasės prietaisus ir IIb klasės implantabilias prietaisus, kurie nėra laikomi gerai įsitvirtinusiomis technologijomis, kaip nurodyta 52 straipsnio 4 dalyje, reikalingas papildomas IX priedo II skyriaus sertifikatas.

BSI vardu, kaip pranešusi įstaiga pagal aukščiau nurodytą reglamentą (pranešusios įstaigos numeris 2797):

Parašas//

Graeme Tunbridge, vyresnysis viceprezidentas, atsakingas už pasaulinę reguliavimo ir kokybės priežiūrą

Pirmojo išdavimo data: **2024-05-13**

Dabartinio išdavimo data: **2024-05-13**

Galiojimo pradžios data: **2024-05-13**

Galiojimo pabaigos data: **2029-05-12**

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ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas, I ir III skyriai
MMDDRR 772264 RR000

Produktų sąrašas: Ila klasės, pagal užsakymą pagaminti ir kiti prietaisai

Produktas (-ai)	Rizikos klasifikavimas
Enterinis maitinimas, vaistų administravimas / Enteriniai siurbimo prietaisai ir priedai	Class IIa

Pirmojo išdavimo data: **2024-05-13**

Dabartinio išdavimo data: **2024-05-13**

Galiojimo pradžios data: **2024-05-13**

Galiojimo pabaigos data: **2029-05-12**

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2 puslapis iš 3

ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas, I ir III skyriai

MMDDRR 772264 RR000

Sertifikato istorija

Sertifikato istorija (Nuorodas į taikomas bendrąsias specifikacijas, suderintus standartus, kurių laikomasi, ir atitinkamas bandymų bei audito ataskaitas, kurios palaiko bet kokius žemiau pateiktus sertifikato pakeitimus, galima prašyti iš Certificate.Verification@bsigroup.com)

Data	Nuorodos numeris	Veiksmai
Dabartinė	3566773	Išleista

Pirmojo išdavimo data: **2024-05-13**

Dabartinio išdavimo data: **2024-05-13**

Galiojimo pradžios data: **2024-05-13**

Galiojimo pabaigos data: **2029-05-12**

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3 puslapis iš 3

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761075 R000

Manufacturer: CAIR LGL

Address:

1 Allée Des Chevreuils
Lissieu
69380
France

Single Registration Number: FR-MF-000007921

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

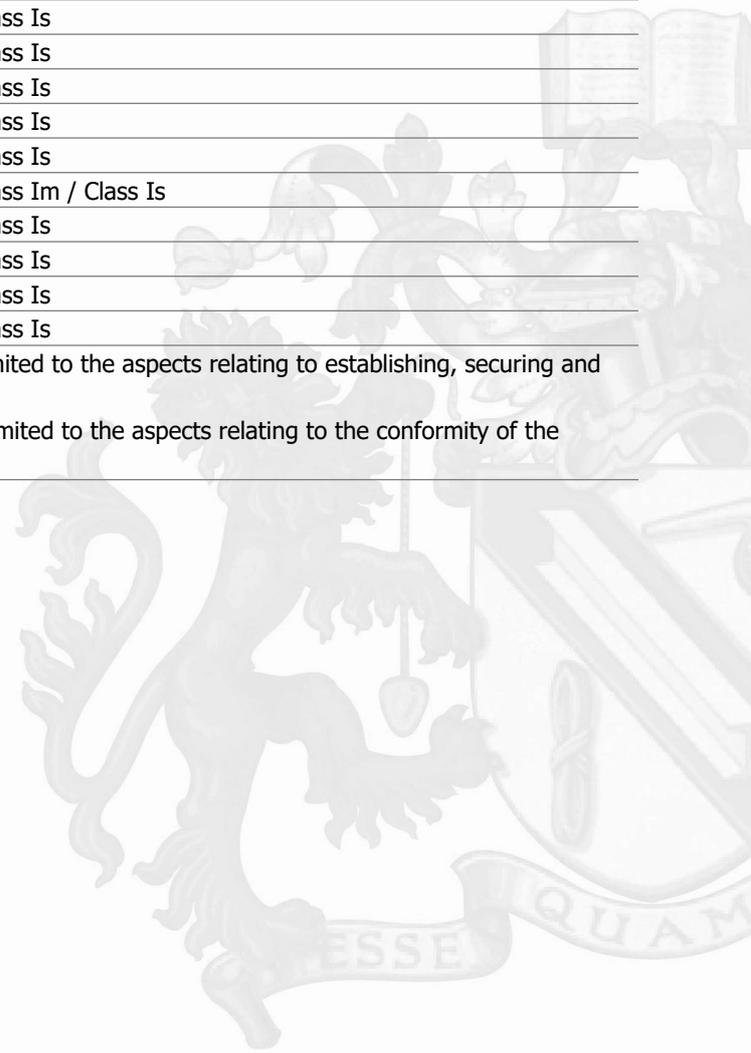
MDR 761075 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Suction and dilatation systems for the respiratory system	Class Is
Drainage and fluid collection devices	Class Is
Intubation devices and accessories	Class Is
Respiratory masks, and balloons and accessories	Class Is
Oxygen administration and humidification systems	Class Is
Tubular devices	Class Im / Class Is
Samples collection devices – various	Class Is
Syringes accessories	Class Is
Adapters, connectors, ramps, stopcocks, caps	Class Is
Newborn nutrition devices	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.



First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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EU Quality Assurance Certificate

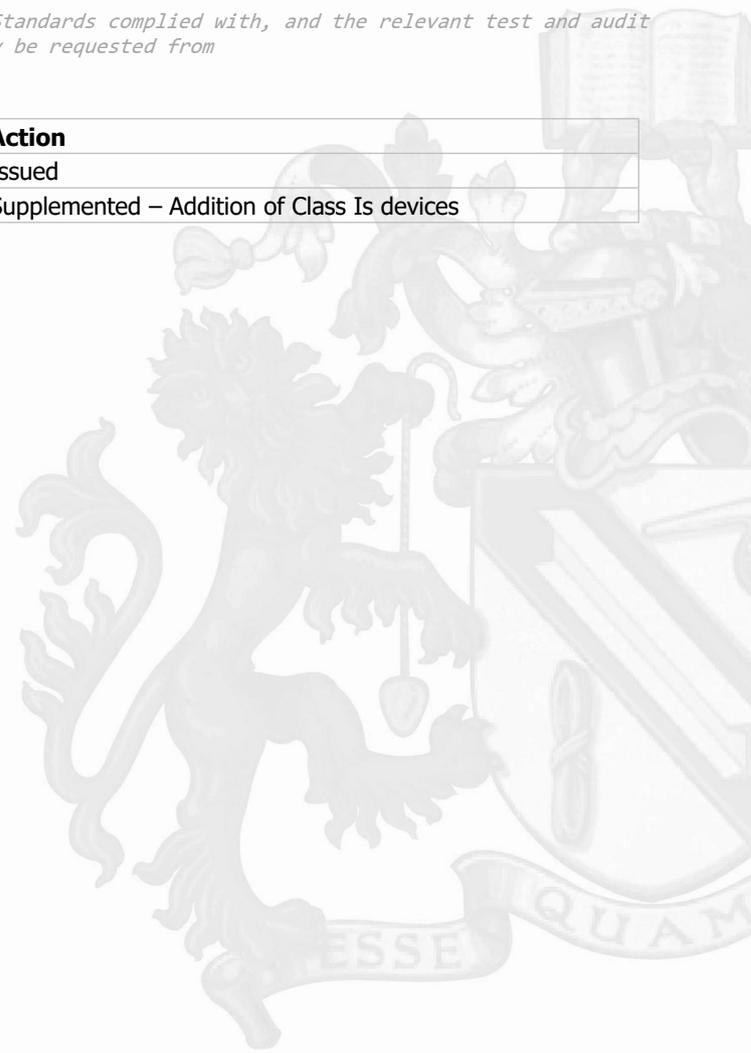
Regulation (EU) 2017/745, Annex XI Part A

MDR 761075 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-09-25	3566773	Issued
Current	30152906	Supplemented – Addition of Class Is devices



First Issue Date: **2023-09-25**

Current Issue Date: **2024-05-09**

Starting Validity Date: **2024-05-09**

Expiry Date: **2028-09-24**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas A dalis

MDR 761075 R000

Gamintojas: CAIR LGL

Adresas:

1 Allée Des Chevreuils

Lissieu

69380

Prancūzija

Bendras registracijos numeris: FR-MF-000007921

Žr. pridedamą **produktų sąrašą**.

Remiantis mūsų kokybės sistemos patikrinimu pagal Reglamentą (ES) 2017/745, XI priedą, A dalį, kokybės sistema atitinka Reglamento reikalavimus. Norint pateikti rinkai III ir IIb klasės prietaisus, reikalingas papildomas X priedo sertifikatas.

BSI vardu, kaip pranešusi įstaiga pagal aukščiau nurodytą reglamentą (pranešusios įstaigos numeris 2797):

Parašas//

Graeme Tunbridge, vyresnysis viceprezidentas, atsakingas už pasaulinę reguliavimo ir kokybės priežiūrą

Pirmojo išdavimo data: **2023-09-25**

Dabartinio išdavimo data: **2024-05-09**

Galiojimo pradžios data: **2024-05-09**

Galiojimo pabaigos data: **2028-09-24**

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1 puslapis iš 3

Šio sertifikato galiojimas priklauso nuo to, ar gamintojo kokybės sistema yra palaikoma pagal Reglamento reikalavimus, kaip parodyta notifikuotos įstaigos reikalaujamų priežiūros veiklų metu. Šis sertifikatas buvo išduotas elektroniniu būdu ir yra susijęs su sutarties sąlygomis.

Notifikuotos įstaigos kontaktai: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdamas, Nyderlandai. Tel: + 31 (0) 20 346 07 80 Korporatyviniai kontaktai: BSI Group Assurance Limited, registruota Anglijoje, numeris 05435540, adresu 389 Chiswick High Road, Londonas, W4 4AL, JK. BSI Group įmonių grupės narys.

ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas A dalis

MDR 761075 R000

Prietaisų sąrašas: Ila klasės, pagal užsakymą pagaminti ir kiti produktai

Produktas (-ai)	Rizikų klasifikacija
Siurbimo ir išplėtimo (dilatacijos) sistemos kvėpavimo sistemai	Is klasė
Drenažo ir skysčių surinkimo prietaisai	Is klasė
Intubacijos prietaisai ir priedai	Is klasė
Kvėpavimo kaukės (respiratoriai), balionai ir priedai	Is klasė
Deguonies tiekimo ir drėkinimo sistemos	Is klasė
Vamzdelių prietaisai	Im klasė / Is klasė
Mėginių surinkimo prietaisai – įvairūs	Is klasė
Švirkštų priedai	Is klasė
Adapteriai, jungtys, rampos, stopcock kraneliai, dangteliai	Is klasė
Naujagimių mitybos produktai	Is klasė

Klasės Is prietaisams Notifikuotosios įstaigos atitikties vertinimas apsiriboja aspektais, susijusiais su sterilumo sąlygų nustatymu, užtikrinimu ir palaikymu.

Klasės Im prietaisams Notifikuotosios įstaigos atitikties vertinimas apsiriboja aspektais, susijusiais su prietaisų atitiktimi metrologiniams reikalavimams.

Pirmojo išdavimo data: **2023-09-25**

Dabartinio išdavimo data: **2024-05-09**

Galiojimo pradžios data: **2024-05-09**

Galiojimo pabaigos data: **2028-09-24**

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2 puslapis iš 3

ES Kokybės vadybos sistemos sertifikatas

Reglamentas (ES) 2017/745, IX priedas A dalis

MDR 761075 R000

Sertifikato istorija

Sertifikato istorija (Nuorodas į taikomas bendrąsias specifikacijas, suderintus standartus, kurių laikomasi, ir atitinkamas bandymų bei audito ataskaitas, kurios palaiko bet kokius žemiau pateiktus sertifikato pakeitimus, galima prašyti iš Certificate.Verification@bsigroup.com)

Data	Nuorodos numeris	Veiksmai
2023-09-25	3566773	Išleista
Dabar	30152906	Papildyta - Is klasės prietaisų įtraukimas



Pirmojo išdavimo data: **2023-09-25**

Dabartinio išdavimo data: **2024-05-09**

Galiojimo pradžios data: **2024-05-09**

Galiojimo pabaigos data: **2028-09-24**

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3 puslapis iš 3

Šio sertifikato galiojimas priklauso nuo to, ar gamintojo kokybės sistema yra palaikoma pagal Reglamentas reikalavimus, kaip parodyta notifikuotos įstaigos reikalaujamų priežiūros veiklų metu. Šis sertifikatas buvo išduotas elektroniniu būdu ir yra susijęs su sutarties sąlygomis.

Notifikuotos įstaigos kontaktai: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdamas, Nyderlandai. Tel: + 31 (0) 20 346 07 80 Korporatyviniai kontaktai: BSI Group Assurance Limited, registruota Anglijoje, numeris 05435540, adresu 389 Chiswick High Road, Londonas, W4 4AL, JK. BSI Group įmonių grupės narys.

DEKLARACJA ZGODNOŚCI UE
EU DECLARATION OF CONFORMITY



NR DEKLARACJI <i>No. Declaration</i>	01/2021
NAZWA PRODUCENTA <i>Name and address of the manufacturer</i>	Esvico Sp. z o.o. ul. Chmieleniecka 15 84-214 Bożepole Wielkie woj. pomorskie, Polska
NAZWA PRODUKTU I NAZWA HANDLOWA <i>Product and trade name</i>	JEDNORAZOWE ELEKTRODY EKG <i>Disposable ECG electrodes</i>
MODEL / TYP <i>Type / Model</i>	GS,GM,WS,WM,GST,GMT,WST,WMT,
WYMIARY <i>Dimension</i>	Okrągłe / round: 24,30, 36, 40, 43, 48,50,54 (mm) Prostokątne / rectangular: 22x45; 36x48; 42x56
NUMER KATALOGOWY (REF) <i>Catalogue number</i>	ES GS24 – ES GS54; ES GS 2245; ES GS3648; ESGS4256 ES GS24T – ES GS54T; ES GS 2245T; ES GS3648T; ESGS4256T ES GM24 – ES GM54;ES GM2245; ES GM3648; ES GM4256 ES GM24T – ES GM54T;ES GM2245T; ES GM3648T; ES GM4256T ES WS 24 – ES WS54; ES WS2245; ES WS3648; ES WS4256 ES WS 24T – ES WS54T; ES WS2245T; ES WS3648T; ES WS4256T ES WM24 – ES WM54; ES WM2245; ES WM3648; ES WM4256 ES WM24T – ES WM54T; ES WM2245T; ES WM3648T; ES WM4256 T
KLASA RYZYKA WYROBU <i>Risk class of the device</i>	KLASA I
Kod GMDN <i>GMDN Code</i>	35035
Nazwa rodzajowa GMDN <i>GMDN Term name</i>	Elektroda elektrokardiograficzna, jednorazowego użytku <i>Electrocardiographic electrode, single-use</i>
<p>Deklarujemy na własną odpowiedzialność, że przedmiot niniejszej deklaracji zgodności UE jest zgodny z ROZPORZĄDZENIEM PARLAMENTU EUROPEJSKIEGO I RADY (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych, zmiany dyrektywy 2001/83/WE, rozporządzenia (WE) nr 178/2002 i rozporządzenia (WE) nr 1223/2009 oraz uchylecia dyrektyw Rady 90/385/EWG i 93/42/EWG.</p> <p>We declare on our own responsibility that the subject of this EU declaration of conformity conforms to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.</p>	
Zastosowane normy zharmonizowane, inne normy: <i>Harmonized standards applied</i>	PN-EN ISO 10993-1:2010 / EN ISO 10993-1:2009 PN-EN ISO 13485:2016-04, PN-EN ISO 13485:2016-04/AC / EN ISO 13485:2016 PN-EN ISO 14971:2020-05 / EN ISO 14971:2019 PN-EN ISO 15223-1:2017-02 / EN ISO 15223-1:2016 PN-EN ISO 9000 AAMI EC 12
Bożepole Wielkie, 16.03.2021	
MIEJSCE, DATA WYDANIA DEKLARACJI <i>Place, date of issue of the declaration</i>	

CE ATITIKTIES DEKLARACIJA



Deklaracijos numeris	01/2021
Gamintojo pavadinimas ir adresas	Esvico Sp. z o.o. ul. Chmieleniecka 15 84-214 Bożepole Wielkie woj. pomorskie, Lenkija
Produktas ir jo pavadinimas	Vienkartiniai EKG elektrodai
Tipas/modelis	GS,GM,WS,WM,GST,GMT,WST,WMT,
Išmatavimai	Apvalūs: 24,30, 36, 40, 43, 48,50,54 (mm) Stačiakampiai: 22x45; 36x48; 42x56
Katalogo numeriai	ES GS24 - ES GS54; ES GS 2245; ES GS3648; ESGS4256 ES GS24T - ES GS54T; ES GS 2245T; ES GS3648T; ESGS4256T ES GM24 - ES GM54;ES GM2245; ES GM3648; ES GM4256 ES GM24T - ES GM54T;ES GM2245T; ES GM3648T; ES GM4256T ES WS 24 - ES WS54; ES WS2245; ES WS3648; ES WS4256 ES WS 24T - ES WS54T; ES WS2245T; ES WS3648T; ES WS4256T ES WM24 - ES WM54; ES WM2245; ES WM3648; ES WM4256 ES WM24T - ES WM54T; ES WM2245T; ES WM3648T; ES WM4256 T
Prietaiso rizikos klasė	KLASĖ I
GMDN kodas	35035
GMDN termino pavadinimas	<i>Elektrokardiografinis elektrodas, vienkartinis</i>
<p><i>Savo atsakomybe pareiškiame, kad šios ES atitikties deklaracijos objektas atitinka 2017 m. balandžio 5 d. EUROPOS PARLAMENTO IR TARYBOS REGLAMENTĄ (ES) 2017/745 dėl medicinos prietaisų, iš dalies keičiantis Direktyvą 2001/83/EB, Reglamentą (EB) Nr. 178/2002 ir Reglamentą (EB) Nr. 1223/2009 ir panaikinantis Tarybos direktyvas 90/385/EEB ir 93/42/EEB.</i></p>	
Taikyti darnieji standartai	PN-EN ISO 10993-1:2010 / EN ISO 10993-1:2009 PN-EN ISO 13485:2016-04, PN-EN ISO 13485:2016-04/AC / EN ISO 13485:2016 PN-EN ISO 14971:2013 PN-EN ISO 15223-1:2016 PN-EN ISO 9001:2015 AAMI EC 12
Bożepole Wielkie, 16.03.2021	
Vieta, deklaracijos išdavimo data	



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 098746 0003 Rev. 00

Manufacturer: **Exact Medical Manufacturing, Inc**
No.21 Qingjiang Road, Xinbei District
213000 Changzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000001406

Authorized Representative: Exact Medical Manufacturing B.V.
Kerkstraat 35, 5253 AN NIEUWKUIJK, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.

As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

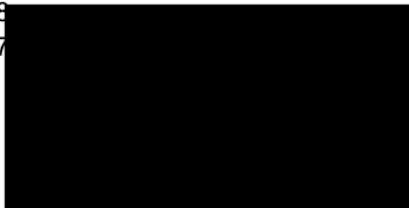
The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21_098746_0003_Rev._00

Report No.: SH21117802

Valid from: 2022-03-18

Valid until: 2027-03-17



Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-18



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
 (Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 098746 0003 Rev. 00

Classification:	I
Device Group:	T02010101 - INCISION DRAPES, WITHOUT ANTIBACTERIAL AGENT T020199 - SURGICAL DRAPES - OTHER T020401 - STANDARD SURGICAL GOWNS T020402 - REINFORCED SURGICAL GOWNS T030101 - COVER CAPS, INSTRUMENTS AND EQUIPMENT T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate /
 depends on conditions and/or
 is limited to the following:

ES Kokybės Užtikrinimo Sertifikatas (MDR)

Pagal Reglamento (ES) 2017/745 dėl medicinos prietaisų XI priedo A dalį
(I klasės prietaisai sterilūs, su matavimo funkcija arba daugkartiniai chirurginiai instrumentai)
Nr. G21 098746 0003 Perž. 00

Gamintojas: **Exact Medical Manufacturing, Inc.**

Nr.21 Qingjiang Road, Xinbei rajonas
213000 Changzhou, Jiangsu provincija
KINIJOS LIAUDIES RESPUBLIKA

Gamintojo SRN: CN-MF-000001406

Įgaliotasis

Exact Medical Manufacturing B.V.

Atstovas:

Kerkstraat 35, 5253 AN NIEUWKUIJK, NYDERLANDAI

TÜV SÜD Product Service GmbH sertifikavimo įstaiga patvirtina, kad gamintojas sukūrė, dokumentavo ir įdiegė kokybės valdymo sistemą, kaip aprašyta straipsnyje Reglamento (ES) 2017/745 dėl medicinos prietaisų 10 straipsnio 9 dalį. Išsami informacija apie įrenginių kategorijas kokybės vadybos sistema yra aprašyti kitame (-iuose) puslapyje (-iuose).

Toliau nurodytoje ataskaitoje apibendrinami vertinimo rezultatai ir pateikiama nuoroda į atitinkamus CS, darniuosius standartus ir bandymų ataskaitas. Atitiktis vertinimas buvo atliktas pagal šios taisyklės XI priedo A dalį su teigiamu rezultatu.

Jei taikoma, notifikuotoji įstaiga dalyvauja tik šiais aspektais, susijusiais su:

- sterilių sąlygų sukūrimas, užtikrinimas ir palaikymas,
- prietaisų atitiktis metrologiniams reikalavimams,
- pakartotinis prietaiso naudojimas, ypač valymas, dezinfekavimas, sterilizavimas, priežiūra ir veikimo bandymas ir susijusios naudojimo instrukcijos.

Sertifikuota kokybės užtikrinimo sistema yra periodiškai prižiūrima TÜV SÜD Product Service GmbH. Visi taikomų TÜV SÜD testavimo ir sertifikavimo reglamento reikalavimų turi būti laikomasi. Išsamią informaciją ir sertifikato galiojimą rasite: www.tuvsud.com/ps-cert?q=cert: G21 098746 0003 Rev. 00

Protokolo Nr. SH21117802

Galioja nuo: 2022-03-18

Galioja iki: 2027-03-17

/parašas/
Christoph Dicks

Išdavimo data:2022-03-8

Sertifikavimo/Notifikuotos Įstaigos direktorius

TÜV SÜD Product Service GmbH yra notifikuota įstaiga, identifikacijos Nr. 0123

ES Kokybės Užtikrinimo Sertifikatas (MDR)

Pagal Reglamento (ES) 2017/745 dėl medicinos prietaisų XI priedo A dalį
(I klasės prietaisai sterilūs, su matavimo funkcija arba daugkartiniai chirurginiai instrumentai)

Nr. G21 098746 0003 Perž. 00

Klasifikacija: I
Prietaisų grupė: T02010101- INCIZINĖS PLĖVELĖS BE ANTIBAKTERINĖS
VEIKLIOSIOS MEDŽIAGOS
T020199 – CHIRURGINIAI APKLOTAI – KITA
T020401 – STANDARTINIAI CHIRURGINIAI CHALATAI
T020402 – SUSTIPRINTI CHIRURGINIAI CHALATAI
T030101 – DANGALAI, INSTRUMENTAMS IR APARATŪRAI
T030102 – APKLOTAI, INSTRUMENTAMS IR APARATŪRAI
T030199 – DANGALAI, INSTRUMENTAMS IR APARATŪRAI –
KITA
Prietaiso savybės: MDS 1005.1 – Etileno Oksido sterilizacija

Šio sertifikato galiojimas
priklauso nuo sąlygų ir/ar
apsiriboja šiais dalykais: /



Health Technology Certification

EC-CERTIFICATE

PRODUCTION QUALITY ASSURANCE

This is to certify that the
quality management system of

**GRUPA MEDİKAL TEKSTİL TIBBİ
MALZEME İKLİM SAN. VE TİC. LTD. ŞTİ.**

DOĞUŞ CAD. 3/19 SOKAK NO:6 ZEMİN KAT, OSB.
1.BÖLGE BUCA, İZMİR 35400, Turkey

for manufacturing and final testing of

Class I Sterile devices:

- Disposable drapes
- Disposable gowns
- Disposable drape packs
- Equipment covers

fulfills the requirements of Annex V of Council Directive 93/42/EEC.

The use of CE Marking followed by the HTCert Notified Body identification number 2803 for the devices listed on the certificate is hereby authorised. The certificate remains valid subject to satisfactory surveillance audits, periodic or unexpected. Any significant changes in design or manufacture may render this certificate invalid. For class I sterile devices the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate No: 2044C05210101
Issue Date: 25/01/2021
Original Approval: 25/01/2021
Valid until: 26/05/2024
References: W001 2044 01

HTCert is a Notified Body according
to Council Directive 93/42/EEC concerning
medical devices with identification
number 2803

For and on behalf of HTCert

GEORGE PAPPOUS
Managing Director

FILIPPOS KOTTIS
Certification Director

GrupA Medikal Tekstil Tibbi Mal. İklim. San. Ve Tic. Ltd.
Dogus Caddesi 3/19 Kapi No:6 35400 OSB 1.
Bolge, Buca, Izmir, 35400, Türkiye

Date: 24 September 2024

Confirmation Letter
Reference: TR_027332_2024_02

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, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 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:

GrupA Medikal Tekstil Tibbi Mal. İklim. San. Ve Tic. Ltd.Sti.- limited liability company
Dogus Caddesi 3/19 Kapi No:6 35400 OSB 1. Bolge, Buca, Izmir, 35400, Türkiye
SRN: TR-MF-000027332

Application ID: TR_027332_24_03_02
Application Date: 23/04/2024
Contract for MDR certification signed on 12/09/2024

The devices covered by the formal application and the written agreement mentioned above are identified below. HTCert is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

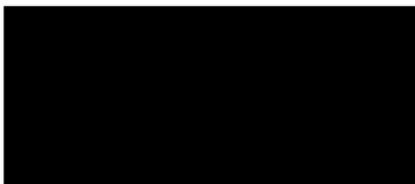
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or 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,



Filippos Kottis
Certification Director

Devices covered by this letter

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Single Use Disposable Surgical Drapes, Gowns, Covers and their Sets	Class Is	n/a	2044C05210101 NB 2803

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/30	TR_027332_2024_01	Initial issue
2024/09/24	TR_027332_2024_02	Addition of the contract details

EU Declaration of Conformity

AB uygunluk beyanı

Manufacturers Name:	Üreticinin ismi	GrupA Medikal Ltd. Sti. (GrupA Medical Co. Ltd.)	
Manufacturers Address:	Üreticinin adresi	Buca OSB mh. Doğuş Caddesi, 3/19. Sk. No:6, Zemin Kat, 35400, Buca Osb/Buca/Izmir, Turkey	
SRN (Single Registration Number):	SRN (Tekil Kayıt numarası)	TR-MF-000027332	
Authorized Representative (if applicable):	Avrupa Birliği yetkili temsilcisi (eğer uygunsuzsa)	Not applicable / Uygulanabilir değil Medical device manufacturers in Turkey do not require a European Union Authorized representative due to the fact that Turkey is a member of the customs union and this is presented in DECISION No 1/2006 OF THE EC-TURKEY ASSOCIATION COUNCIL.	
Authorized Representative Address (if applicable):	Avrupa Birliği yetkili temsilcisi adresi (eğer uygunsuzsa)	Türkiye Cumhuriyeti içerisindeki tıbbi cihaz üreticileri Avrupa Birliğinde bir yetkili temsilciye Türkiye Cumhuriyeti gümrük birliğinin üyesi olduğu için THE EC-TURKEY ASSOCIATION COUNCIL kuruluşunun Karar No 1/2006 sayılı kararı doğrultusunda ihtiyaç duymamaktadır.	
Basic UDI-DI:	Temel tanımlama numarası	1.1. 8682276240742, 8682276240476, 8682276240490 1.2. 8682276240339, 8682276241152 1.3. 8682276240681, 8682276240681, 8682276240438, 8682276240575 1.4. 8682276240650, 8682276240445, 8682276240483, 8682276240674, 8682276240117, 8682276240568 1.5. 8682276240513, 8682276240100, 8682276240537, 8682276240520 1.6. 8682276240483, 8682276240452 1.7. 8682276240544, 8682276240551, 8682276240421, 8682276240209, 8682276240230, 1.8. 8682276240698, 8682276240742, 8682276240759, 8682276240292, 8682276240018, 8682276240933, 8682276240957, 8682276241206, 8682276240834, 2. 8682276240025, 8682276240032, 8682276240049, 8682276240056, 8682276240872, 8682276240889, 8682276240070, 8682276240063, 8682276240087, 8682276240094, 8682276240896,	8682276240902, 8682276241213, 8682276241220, 8682276241237, 8682276241244, 8682276240032, 3.1. 8682276240346, 8682276240131, 8682276240148, 3.2. 8682276240278, 8682276240353, 3.3. 8682276240384, 8682276240254, 8682276240155, 8682276240612, 8682276240261, 3.4. 8682276240162, 8682276240216, 8682276240179, 8682276240223, 8682276240605, 3.5. 8682276240360, 8682276240124, 8682276240230, 8682276240247, 3.6. 8,682276240186, 8682276240377, 3.7. 8682276240193, 8682276240391, 8682276240643, 8682276240209, 3.8. 8682276241367, 3.9. 8682276240964, 4. 8682276240926, 8682276240919 8682276240919, 8682276240919, 8682276240940, 5. 8682276240407, 6. 8682276240414, 8682276240773

Name of the Device (s):	Cihazların ismi	<p>1. SURGICAL DRAPES</p> <p>1.1. CATEGORY: GENERAL SURGERY ADHESIVE DRAPE, LAPAROTOMY DRAPE, LAPAROSCOPY DRAPE</p> <p>1.2. CATEGORY: OPHTHALMOLOGY LASIC DRAPE, OPHTHALMIC DRAPE</p> <p>1.3. CATEGORY: CARDIOLOGY CARDIOVASCULAR DRAPE, BY-PASS DRAPE, VALVE REPLACEMENT DRAPE, ANGIOGRAPHY DRAPE, THORAX DRAPE</p> <p>1.4. CATEGORY: ORTHOPEDICS U-SPLIT (HIP) DRAPE, EXTREMITY DRAPE, ARTHROSCOPY DRAPE, SHOULDER ARTHROSCOPY DRAPE, VERTICAL ISOLATION DRAPE, HAND/FOOT DRAPE</p> <p>1.5. CATEGORY: UROLOGY UROLOGY DRAPE, TUR DRAPE, CYSTOSCOPY DRAPE, PERCUTANEOUS DRAPE</p> <p>1.6. CATEGORY: NEUROSURGERY CRANIOTOMY DRAPE, LAMINECTOMY DRAPE</p> <p>1.7. CATEGORY: GYNECOLOGY CEASEREAN DRAPE, GYNECOLOGY DRAPE, OPU DRAPE, BABY DRAPE, DELIVERY DRAPE ACCESSORIES</p> <p>1.8. CASES & OTHERS: PLAIN DRAPE, ADHESIVE DRAPE, FENESTRATED DRAPE, BACK TABLE COVER, MAYO TABLE COVER, LEGGINGS, STOCKINETTE, HAND TOWEL, NON-WOVEN ADHESIVE TAPE / OP TAPE)</p>
		<p>2. SURGICAL GOWNS SIZES: S,M,L,XL,XXL,XXXL STANDARD SURGICAL GOWN, REINFORCED SURGICAL GOWN, FULLY REINFORCED SURGICAL GOWN, FULL REINFORCED SURGICAL GOWN(SFS), UROLOGY GOWN</p>
		<p>3. SURGICAL DRAPE PACKS</p> <p>3.1. CATEGORY: GENERAL SURGERY LAPAROTOMY PACK, LAPAROSCOPY PACK, GENERAL SURGERY DRAPE PACK</p> <p>3.2. CATEGORY: OPHTHALMOLOGY OPHTHALMIC PACK, CATARACT PACK</p> <p>3.3. CATEGORY: CARDIOLOGY CARDIOLOGY PACK, BY-PASS PACK, VALVE REPLACEMENT PACK, ANGIOGRAPHY PACK, THORAX PACK,</p> <p>3.4. CATEGORY: ORTHOPEDICS HIP PACK, EXTREMITY PACK, ARTHROSCOPY PACK, SHOULDER ARTHROSCOPY PACK, HAND/FOOT PACK,</p> <p>3.5. CATEGORY: UROLOGY UROLOGY PACK, TUR PACK, CYSTOSCOPY PACK, PERCUTANEOUS PACK</p> <p>3.6. CATEGORY: NEUROSURGERY CRANIOTOMY PACK, LAMINECTOMY PACK,</p> <p>3.7. CATEGORY: GYNECOLOGY CEASEREAN PACK, GYNECOLOGY PACK, OPU PACK, DELIVERY PACK,</p> <p>3.8. CATEGORY: E.N.T E.N.T PACK</p> <p>3.9. CATEGORY: DENTAL DENTAL IMPLANT DRAPE PACK</p>
		<p>4. EQUIPMENT COVERS FLUOROSCOPY COVER, EQUIPMENT COVER, X-RAY CASSETTE COVER, DIATHERMY BAG WITH CORD FASTENER, LIQUID COLLECTION POUCH, C-ARM COVER</p>
		<p>5. CAMERA COVER</p>
		<p>6. MICROSCOPE COVER</p>

Product code:	Cihazların kodu	GMDN: 1.1-1.8: 47783 2: 35778 3.1-3.9: 47783 4: 37450 5: 37450 6: 37450	EMDN: 1.1-1.8: T020102 2: T020402 3.1-3.9: T020102 4: T030101 5: T030101 6: T030101
Classification:	Cihazların sınıflandırması	Class I sterile according to Annex VIII rule 1 of Medical Device Regulation 2017/745/EU (which requires notified body intervention) 2017/745/EU Tıbbi Cihaz Yönetmeliği Ek VIII kural 1'e göre Sınıf I steril. (onaylanmış kuruluş müdahalesi gerektirir.)	
Notified Body name:	Onaylanmış kuruluş ismi	HTCert (Health Technology Certification Ltd)	
Notified Body Address:	Onaylanmış kuruluş adresi	Jacovides Tower. 81-83 Grivas Dighenis Av. Cy-1090. Nicosia, Cyprus	
Notified Body Identification number:	Onaylanmış kuruluş numarası:	2803	
CE Certificate number:	CE Sertifikası Numarası:	2044C05210101	
Conformity assessment route:		Uygunluk değerlendirme yöntemi	
GrupA Medikal Ltd. Sti. (GrupA Medical Co. Ltd.) uses the following procedures for the CE-labeling of their products according to Regulation MDR 2017/745(EU): Class I: EU conformity declaration according to Annex IV Devices are evaluated according to Article 120 of (EU)2017/745 for the transition from Annex V of 93/42/EEC with valid certification.			
GrupA Medikal Ltd. Sti. (GrupA Medical Co. Ltd.) ekte bulunan listedeki ürünlerinin tıbbi cihaz tüzüğü 2017/745(EU) düzenlemesine göre CE işaretleme için aşağıdaki değerlendirme yöntemini kullanmaktadır. Sınıfı I: AB uygunluk beyanı IV sayılı yönetmelik ekine göre gerçekleştirilmiştir. Cihazlar, 93/42/EEC ek V'e göre sunulmuş geçerli belgesi ile geçiş için (EU)2017/745 madde 120'ye göre değerlendirilmektedir.			
This declaration of conformity is issued under the sole responsibility of GrupA Medikal Ltd. Sti. (GrupA Medical Co. Ltd.). We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the certificate issued by HTCert (Health Technology Certification Ltd) (certificate number:2044C05210101) for Annex V of 93/42/EEC. All supporting documentation is retained at the premises of the manufacturer.			
Bu uygunluk beyanı GrupA Medikal Ltd. Sti. (GrupA Medical Co. Ltd.) sorumluluğu altında düzenlenmiştir. Burada beyan etmekteyiz ki yukarıda bilgileri verilen tıbbi cihazlar üzerine Avrupa Birliği tarafından sunulan (EU)2017/745 sayılı düzenleme olan tıbbi cihazlar tüzüğüne şartlarını yerine getirmektedir. Bu beyan ISO 13485:2016 kalite yönetim sistemi standardına göre hazırlanmış HTCert (Health Technology Certification Ltd) (#, No: 2044C05210101) tarafından sunulan onaya göre 93/42/EEC Ek V'e göre belgelendirilmiş bir EC (Avrupa'ya uygunluk) sertifikasına dayandırılmaktadır. Bütün destekleyici dokümantasyon üreticinin tesislerinde saklanmaktadır.			
Signature	İmza	Feridun	Place and date of issue:
Name	İsim	Genel	Yer ve tarihi:
Function	Görev	Genera	İstanbul, Turkey, 01.05.2024

Attachment to the declaration of conformity ...

Uygunluk beyanının eki ...

Product Code	Basic UDI-DI	Description
1. Surgical Drapes		
1.1. General Surgery		
GD.303.021.S	8682276240742	Adhesive Drape
GD.212.001.S	8682276240476	Laparotomy Drape
GD.282.001.S	8682276240490	Laparoscopy Drape
1.2. Ophthalmology		
GD.230.001.S	8682276240339	Lasic Drape
GD.232.004.S	8682276241152	Ophthalmic Drape
1.3. Cardiology Drape		
GD.220.001.S	8682276240681	Cardiovascular Drape
GD.220.002.S	8682276240681	By-Pass Drape
GD.220.003.S	8682276240681	Valve Replacement Drape
GD.223.001.S	8682276240438	Angiography Drape
GD.222.001.S	8682276240575	Thorax Drape
1.4. Orthopaedics		
GD.353.001.S	8682276240650	U-Split (Hip) Drape
GD.265.001.S	8682276240445	Extremity Drape
GD.240.001.S	8682276240483	Arthroscopy Drape
GD.261.001.S	8682276240674	Shoulder Arthroscopy Drape
GD.264.002.S	8682276240674	Vertical Isolation Drape
GD.266.001.S	8682276240568	Hand/Foot Drape
1.5. Urology		
GD.284.001.S	8682276240513	Urology Drape
GD.280.001.S	8682276240100	Tur Drape
GD.281.001.S	8682276240537	Cystoscopy Drape
GD.283.001.S	8682276240520	Percutaneous Drape
1.6. Neurosurgery		
GD.240.001.S	8682276240483	Craniotomy Drape
GD.241.001.S	8682276240452	Laminectomy Drape
1.7. Gynaecology		
GD.271.002.S	8682276240544	Caesarean Drape
GD.273.001.S	8682276240551	Gynaecology Drape
GD.272.001.S	8682276240421	Opu Drape
GD.274.001.S	8682276240209	Baby Drape
GD.275.001.S	8682276240230	Delivery Drape Accessories
1.8. Cases & Others		
GD.303.001.S	8682276240698	Plain Drape
GD.303.021.S	8682276240742	Adhesive Drape
GD.332.001.S	8682276240759	Fenestrated Drape
GD.500.001.S	8682276240292	Back Table Cover
GD.506.001.S	8682276240018	Mayo Table Cover
GD.304.001.S	8682276240933	Legging
GD.305.001.S	8682276240957	Stockinette
GD.306.001.S	8682276241206	Hand Towel

GD.307.001.S	8682276240834	Non-Woven Adhesive Tape / Op Tape)
2. Surgical Gowns		
GG.10.001.S	8682276240025	Standard Surgical Gown (S, M, L, XL, XXL, XXXL)
GG.10.002.S	8682276240032	
GG.10.003.S	8682276240049	
GG.10.004.S	8682276240056	
GG.10.005.S	8682276240872	
GG.10.006.S	8682276240889	
GG.20.001.S	8682276240070	Reinforced Surgical Gown (S, M, L, XL, XXL, XXXL)
GG.20.002.S	8682276240063	
GG.20.003.S	8682276240087	
GG.20.004.S	8682276240094	
GG.20.005.S	8682276240896	
GG.20.006.S	8682276240902	
GG.30.001.S	8682276241213	Full Reinforced Surgical Gown (SFS) (S, M, L, XL)
GG.30.002.S	8682276241220	
GG.30.003.S	8682276241237	
GG.30.004.S	8682276241244	
GG.50.001.S	8682276240032	Urology Gown (Standard)
3. Surgical Drape Packs		
3.1. General Surgery		
GP.112.001.S	8682276240346	Laparotomy Pack
GP.182.001.S	8682276240131	Laparoscopy Pack
GP.110.001.S	8682276240148	General Surgery Drape Pack
3.2. Ophthalmology		
GP.130.001.S	8682276240278	Ophthalmic Pack
GP.130.003.S	8682276240353	Cataract Pack
3.3. Cardiology		
GP.120.002.S	8682276240384	Cardiology Pack
GP.120.001.S	8682276240254	By-Pass Pack
GP.121.001.S	8682276240155	Valve Replacement Pack
GP.122.001.S	8682276240612	Thorax Pack
GP.123.001.S	8682276240261	Angiography Pack
3.4. Orthopaedics		
GP.160.001.S	8682276240162	Hip Pack
GP.165.001.S	8682276240216	Extremity Pack
GP.161.001.S	8682276240179	Arthroscopy Pack
GP.164.001.S	8682276240223	Shoulder Arthroscopy Pack
GP.166.001.S	8682276240605	Hand/Foot Pack
3.5. Urology		
GP.184.001.S	8682276240360	Urology Pack
GP.180.001.S	8682276240124	Tur Pack
GP.181.001.S	8682276240230	Cystoscopy Pack
GP.183.001.S	8682276240247	Percutaneous Pack
3.6. Neurosurgery		
GP.140.001.S	8682276240186	Craniotomy Pack
GP.141.001.S	8682276240377	Laminectomy Pack
3.7. Gynaecology		
GP.171.001.S	8682276240193	Caesarean Pack
GP.173.001.S	8682276240391	Gynecology Pack
GP.172.001.S	8682276240643	Opu Pack

GP.170.001.S	8682276240209	Delivery Pack
3.8. E.N.T		
GP.174.001.S	8682276241367	E.N.T Pack
3.9. Dental		
GP.190.001.S	8682276240964	Dental Implant Drape Pack
4. Equipment Covers		
GC.570.001.S	8682276240926	Fluoroscopy Cover
GC.570.002.S	8682276240919	Equipment Cover
GC.570.003.S	8682276240919	X-Ray Cassette Cover
GC.570.004.S	8682276240919	Diathermy Bag with Cord Fastener
GC.570.005.S	8682276240919	Liquid Collection Pouch
GC.580.001.S	8682276240940	C-Arm Cover
5. Camera Cover		
GC.560.001.S	8682276240407	Camera Cover
6. Microscope Cover		
GC.560.001.S	8682276240414	Microscope Cover Zeiss
GC.563.001.S	8682276240773	Microscope Cover Leica



Product Service

EC Certificate

Production Quality Assurance System

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

No. G2 18 04 14788 026

Manufacturer: **Multimedical s.r.l.**
Zona Ind. Gerbolina

Via G. Rossa 69,71,73
46019 Viadana (MN)
ITALY



Facility(ies): Multimedical s.r.l. Zona Ind. Gerbolina
Via G. Rossa 69,71,73, 46019 Viadana (MN), ITALY

Product Category(ies): Transfusion and infusion sets and associated components: stopcocks, burettes; tubings, extension lines, needles for hemodialysis, paracentesis and thoracentesis, needles for infusion, kit for paracentesis and thoracentesis (needles, syringes and drainage bags), arthroscopy sets, tubing and surgical cannulae for surgical aspiration

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

Report No.: ITA1033875

Valid from: 2018-05-12

Valid until: 2023-05-11



Date, 2018-04-17



Stefan Preiß

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

Page 1 of 1

MULTIMEDICAL s.r.l.
Via Guido Rossa 71, 46019,
Viadana (MN) - ITALIA

2024/04/30

Notified Body Confirmation Letter
Reference: <125333/24 REV.3 >

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, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 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:

MULTIMEDICAL s.r.l.
Via Guido Rossa 71, 46019,
Viadana (MN) - ITALIA
Numero SRN: <: IT-MF-000020128>

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB 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 NB 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 or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or 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,
ICIM SPA

Piazza Don Enrico Mapelli, 75
2099 Sesto San Giovanni MI

Identificazione

su

NANDO

CE0425

Table 1: Devices covered by this letter and for which the NB 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

Table 2: Devices covered by this letter and for which the NB 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
Lines and accessories for gravity infusion	Class <Is>	Gravity infusion sets and associated components, burettes, tubings, extension lines	Certificato G2S 014788 0025 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Lines and accessories for active devices	Class <IIa>	Infusion sets and associated components, burettes, tubings, extension lines	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Lines and accessories for infusion of contrast media	Class <IIa>	Infusion sets and associated components, burettes, tubings, extension lines	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Transfusion controllers	Class <IIa>	Transfusion sets	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Needles for infusion	Class <IIa>	Needles for infusion	Certificato G2 014788 0026 Rev.01

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
			NB: n.0123 TUV SUD Product Service GmbH
Huber needles	Class <IIa>	Needles for infusion	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Kit toracentesi – paracentesi	Classe <IIa>	Kit for paracentesis and thoracentesis (needles, syringe, set and drainage bag)	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Controller for urological irrigation	Classe <Is>	Urology sets	Certificato G2S 014788 0025 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Arthroscopic irrigation controller	Classe <Is>	Athroscopy set	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Parenteral nutrition bags	Classe <Is>	Nutrition bags	Certificato G2S 014788 0025 Rev.01
Tubings and surgical cannulae for surgical aspiration	Classe <IIa>	Tubings and surgical cannulae for surgical aspiration	Certificato G2 014788 0026 Rev.01 NB: n.0123 TUV SUD Product Service GmbH
Elastomeric pumps	Classe <IIa>	Elastomeric infusion pumps	Certificato G1 014788 0503 Rev.00 NB: n.0123 TUV SUD Product Service GmbH

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/04/30		Initial issue

Remaining at your disposal for any clarification on the content of this offer, we take this opportunity to extend our best regards.

Dott. Edoardo Dossena
Product Sales Manager Product

Ing. Flavia Lepore
Direttore Commerciale