Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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 106138 0002 Rev. 00

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class IIb
Double J stent & set
Class IIa
PCN catheter & set
Ureteral catheter
Malecot catheter
Re-entry malecot catheter
Suprapubic catheter
Braided shaft catheter
Dual lumen catheter
Facial dilator
Amplatz dilator & set
Ureteral dilator & set
Ureteral balloon dilator
Double J stent & set
Mono J stent
Endopyelotomy stent
Guidewire
IP Needle
Chiba needle
Stone basket
Perk basket

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.: IND20190101

Valid from: 2020-04-03
Valid until: 2024-05-26

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Legalization see reverse side

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich,
identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00

NOTARIAT ENGE-ZÜRICH · Kanton Zürich ·

NOTARIAT ENGE ZÜRICH

Andreas Bachmann, Notary Public

APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich
   Country: Swiss Confederation, Canton of Zürich
   Diese öffentliche Urkunde / This public document
2. ist unterschrieben von
   has been signed by Andreas Bachmann
3. in seiner Eigenschaft als
   acting in the capacity of Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of
   Notariat Enge – Zürich Kanton Zürich

Bestätigt / Certified

5. In / at 8090 Zürich / Zurich
   6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
   by the Chancellery of State of the Canton of Zürich
8. unter Nr. / under N° 1179274/2020
9. Stempel/Siegel, Stamp/seal
   10. Unterschrift / Signature

THVRICVM SIGILLVM REIPVBLICAE

S. Overkott

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106138 0001 Rev. 00

Holder of Certificate: **Marflow AG**
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Facility(ies): Marflow AG
Soodstrasse 57, 8134 Adliswil, Zurich, SWITZERLAND

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Supply of Medical Disposables, Surgical Tools, Equipment & Accessories in the Field of Urology, Gastroenterology, Radiology, Gynaecology & Cardiology.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2023-04-02

Date, 2020-04-03

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Legalization see reverse side

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich,
identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00

NOTARIAT ENGE-ZÜRICH

NOTARIAT ENGE
Kanton Zürich

APOSTILLE
(Convention de la Haye du 5 octobre 1961)

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4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of
   Notariat Enge – Zürich Kanton Zürich

Bestätigt / Certified
5. In / at 8090 Zürich / Zurich
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7. durch die Staatskanzlei des Kantons Zürich
   by the Chancellery of State of the Canton of Zürich
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10. Unterschrift / Signature

S. Overkott

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 106138 0003 Rev. 00

Manufacturer:

Marflow AG
Soodstrasse 57
8134 Adliswil, Zurich
SWITZERLAND

Product Category(ies):

Class Is
Urine bag connector
Penile clamp
Evacuator
IUI catheter without syringe

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: IND20190101

Valid from: 2020-04-03
Valid until: 2024-05-26

Date, 2020-04-03

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Legalization see reverse side

Official Certification

Seen for authentication of the foregoing signature, acknowledged in our presence by

Ms. **Tracey WALTHER**, born 28th December 1958, Swiss citizen of Oberentfelden AG, according to her information residing at Brunaustrasse 17, 8002 Zürich,
identified by identity card.

Zürich, 8th April 2020
BK no. 1027ff
Fee CHF 20.00

NOTARIAT ENGE-ZÜRICH

NOTARIAT ENGE-ZÜ
Kanton Zürich

APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Land: Schweizerische Eidgenossenschaft, Kanton Zürich
   Country: Swiss Confederation, Canton of Zürich
   Diese öffentliche Urkunde / This public document
2. ist unterschrieben von
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   acting in the capacity of Notary Public
4. sie ist versehen mit dem Stempel/Siegel des (der) – bears the stamp/seal of
   Notariat Enge – Zürich Kanton Zürich

Bestätigt / Certified
5. In / at 8090 Zürich / Zurich
6. am / the 08.04.2020
7. durch die Staatskanzlei des Kantons Zürich
   by the Chancellery of State of the Canton of Zurich
8. unter Nr. / under N° 1179273/2020
9. Stempel/Siegel, Stamp/seal
10. Unterschrift / Signature

S. Overkott

Benannt durch/Designated by
Zentralstelle der Ldnder fUr Gesundheltsschutz bel Arznelmltteln und Medlzlnprodukten
www.zlg.de

ZLG-BS-244.10.08

Product Service

CE Sertifikatas

Produkto kokybės užtikrinimo sistema
Medicinos prietaisų Direktyva 93/42/EEC, Priedas II, išskyrus (4) skirsnį
(IIa, IIb ar III klasės priemonės)

Nr. G1 106138 0002 Perž. 00

Gamintojas: **Marflow AG**
Sood g. 57
8134 Adliswilis, Ciurichas
Šveicarija

Produkto kategorija (-os):

IIb klasė
Dvigubas J formos stentas ir jų rinkiniai
IIa klasė
PCN kateteriai ir jų rinkiniai
Ureteriniai kateteriai
Malecot tipo kateteriai
Pakartotinio įvedimo Malecot tipo kateteriai
Suprapubiniai kateteriai
Pintas kateteris
Dviejų kanalų kateteriai
Fascijų plėtėjai
Amplatz plėtėjai ir jų rinkiniai
Ureteriniai plėtėjai ir jų rinkiniai
Ureteriniai balioniniai plėtėjai
Dvigubas J tipo stentas ir jų rinkiniai
Viengubas J tipo stentas
Endopelotominis stentas
Viela-pravedėjas
IP adata
Chiba adata
Akmenų ištraukimo krepšelis
Perk krepšelis

Notifikuotoji įstaiga TUV SUD Product Service GmbH pareiškia, kad anksčiau minėtas gamintojas įdiegė produktų dizaino, gamybos ir galutinio atitinkamų prietaisų patikrinimo kokybės užtikrinimo sistemą, pagal Direktyvos II priedą. Ši kokybės Sistema apima prietaisų periodinių patikrinimų aspektus, kaip nurodyta Direktyvoje. III klasės prietaisų prekybai papildomai yra privalomas Direktyvos II priedo (4) sertifikatas. Žiūrėti pastabas kitoje pusėje.

Ataskaita Nr.: IND20190101

Galioja nuo: 2020-04-03
Galioja iki: 2024-05-26

TUV SUD Product Service GmbH yra Notifikuotoji institucija, identifikacinis Nr. 0123

Benannt durch/Designated by
Zentralstelle der Ldnder
fUr Gesundheltsschutz
bel Arznelmltteln und
Medlzlnprodukten
www.zlg.de

ZLG-BS-244.10.08

Product Service

CE Sertifikatas

Produkto kokybės užtikrinimo sistema
Medicinos prietaisų Direktyva 93/42/EEC, Priedas II, išskyrus (4) skirsnį
(I klasės sterilios priemonės, sistemos ar procedūrų rinkiniai)

Nr. G1S 106138 0003 Perž. 00

Gamintojas: **Marflow AG**
Sood g. 57
8134 Adliswilis, Ciurichas
Šveicarija

Produkto kategorija (-os):

Is klasė
Šlapimo surinkimo maišo jungtis
Varpos spaustukas
Ištraukėjas
IUI kateteris be švirkšto

Notifikuotoji įstaiga TUV SUD Product Service GmbH pareiškia, kad anksčiau minėtas gamintojas įdiegė produktų dizaino, gamybos ir galutinio atitinkamų prietaisų patikrinimo kokybės užtikrinimo sistemą, pagal Direktyvos II priedą. Ši kokybės Sistema apima prietaisų gamybos aspektus, susijusius su sterilių sąlygų užtikrinimu ir palaikymu, kaip nurodyta Direktyvoje. Atitinkamai kokybės Sistema yra periodiškai tikrinama. Žiūrėti pastabas kitoje pusėje.

Ataskaita Nr.: IND20190101

Galioja nuo: 2020-04-03
Galioja iki: 2024-05-26

Data, 2020-04-03

No

TUV SUD Product Service GmbH yra Notifikuotoji institucija, identifikacinis Nr. 0123

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
106138	TPS1896_IIa	Rajkumar.JSI@tuvsud.com	--	2024-05-22	1 of 4

Marflow AG
Alte Landstrasse 54,
8546 Islikon,
Switzerland

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: TPS1896_IIa

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following

SRN Number: CH-MF-000023766

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.
To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-22

TÜV SÜD Product Service GmbH
Medical and Health Services

_____

JSI. Rajkumar
Conformity Assessment Responsible (CARE)

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device name or Basic UDI-DI (under MDR application)
PCN Catheter & Set, 76300006015KB
Ureteral Catheter, 76300006013K7
Malecot Catheter, 76300006010JZ
Re- Malecot Catheter, 76300006012K5
Suprapubic Catheter, 76300006016KD
Braided Shaft Catheter (Ureteral Access Sheath), 76300006004K6
Dual Lumen Catheter, 76300006069L2
Fascial Dilator, 76300006008KE
Amplatz Dilator & Set, 76300006027KJ
Ureteral Dilator & Set, 76300006029KN
Ureteral Balloon Dilator, 76300006005K8
Double J Stent & Set, 76300006030K7
Mono J Stent, 76300006006KA
Endopyelotomy Stent, 76300006018KH
Guidewire, 76300006023KA

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
IP Needle, 76300006002K2
Chiba Needle, 76300006001JY
Stone Basket, 76300006020K4
Perk basket, 76300006003K4
Nasal Biliary Drainage Catheter, 76300006076KX
Percutaneous Transhepatic Biliary Drainage Catheter & Set, 76300006079L5
Jejunal Feeding Tube, 76300006075KV
Bilbao Dotter, 76300006078L3
Sclerotherapy Needle, 76300006077KZ
Biliary Pusher/ Deployer, 76300006082KS
Gastro Stone Basket, 76300006055KP
PEG Kit, 76300006047KQ
Loop Basket, 76300006046KN
Gastro Forceps, 76300006072KP
Gastro Balloon Dilator, 76300006080KN
Gastro Guidewire, 76300006024KC

Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

Device name or Basic UDI-DI (under MDR application)
Esophageal Dilator, 76300006048KS
PTA Balloon Catheter, 76300006042KE
Double J Stent & Set, 76300006085KY
Urine Bag Connector, 76300006120K9
Penile Clamp, 76300006128KR
IUI Catheter without Syringe, 76300006097L7
Evacuator, 76300006099LB

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 038814 0086 Rev. 01

Manufacturer:

Well Lead Medical Co., Ltd.
C-4 Jinhu Industrial Estate, Hualong
511434 Panyu, Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Urethral Catheter，Connecting Tube with or without Yankauer Handle, Silicone Stomach Tube, Nelaton Catheter, Suction ToothBrush, Capnography CO2 Sampling Mask, O2+CO2 Sampling Cannula, Bile T-Tube, Intermittent Catheter, Tracheal Tube, Endotracheal Tube Kit, Reinforced Endotracheal Tube, Endotracheal Tube with Evacuation Lumen, Laryngeal Mask Device, Intubating Stylet, Endotracheal Tube Introducer, Endobronchial Tube, Endobronchial Blocker Tube

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. 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:G1 038814 0086 Rev. 01

Report No.: SH2008002

Valid from: 2021-02-19

Valid until: 2024-05-26

Date, 2021-02-19

Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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wellead 维力

Document Nr.: WL-DOC-061/C

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Repre-sentative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, GERMANY
Product Name:	Bile T-Tube
Size:	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr, 28Fr, 30Fr
UMDNS Code:	14230

Classification (MDD, Annex IX): **IIa, Rule 7**

Conformity Assessment Route: **Annex II excluding (4)**

We herewith declare in our sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

DIRECTIVES

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	**G1 038814 0086 Rev.01**
Expire date of the Certificate:	**2024-05-26**
Start of CE Marking:	**2013**
Place, Date of Issue:	**Guangzhou, 2021-06-08**

Signature: ___

Name: Chen Yun Gui

Position: **Management Representative**

WELL LEAD MEDICAL CO. LTD. 广州维力医疗器械股份有限公司

Add: C-4# Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Tel: +86 20 84758878
Web: http://www.welllead.com.cn/

Manufacturer's Declaration in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medicoplast International GmbH
Manufacturer address and contact details	Heusweilerstraße 100 66557 Illingen Germany
Single Registration Number (SRN) (if available)	DE-MF-000000174

Notified body name (if applicable)	mdc Medical Device Certification GmbH
Notified body number (if applicable)	0483
Directive Certificate number(s) to which this confirmation is made (if applicable)	1189DE410200616 1189GB410200616 1189DE414210525A 1189GB414210525A 1189DE415210525A 1189GB415210525A
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024.05.27
End date of extended validity/transition period	2028.12.31

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met ***and/or***[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires ***after*** 20 March 2023:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Medicoplast International GmbH, Heusweilerstraße 100, 66557 Illingen, Germany

Illingen, 2

(Mr. Nico Binkle, Head of Regulatory Affairs, PRRC), info@medicoplast.de

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

MDD Device name or REF	MDD Certificate Reference of the MDD device	Is the device under MDR replaced (substituted) with another device – please identify the corresponding substitute device	Maximum Transition timeline as per in Article 120.3c of MDR (as amended by EU 2023/607)
Tracheostomie Tubus mit Cuff mit Armierung verschiebbare Halteplatte 4061961A2BTK0008J4	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomie Tubus ohne Cuff mit Armierung verschiebbare Halteplatte 4061961A2BTK0007J2	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomie Tubus Innenkanüle 4061961A2BTK0002BK	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomie Tubus Biesalski Innenkanüle 4061961A2BTKB002FA	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomie Tubus Biesalski Sprechventil 4061961A2BTKB003FC	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Tracheostomie Tubus Biesalski ohne Cuff ohne Armierung feste Halteplatte 4061961A2BTKB004FE	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomie Tubus Biesalski ohne Cuff ohne Armierung feste Halteplatte 4061961A2BTKB001F8	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheostomietubus bulk unsteril 4061961A2UTK0001ML	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Uretersplint steuerbar 4061961U2BUK0005SJ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Uretersplint steuerbar 4061961U2BUK0006SL	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Uretersplint 4061961U2BUK0001SA	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Uretersplint 4061961U2BUK0003SE	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nephrostomy Set 4061961U2BNSK004Y3	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nephrostomie-Dilatations-Set 4061961U2BNSK005Y5	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Ureterokutaneostomiekatheter 4061961U2BUKS001ZQ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
DLTK links 4061961A2BTK0009BZ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
DLTK rechts 4061961A2BTK0008BX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Endotrachealtuben ohne Cuff 4061961A2AETT001FM	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Real Trachealtuben oral 4061961A2ARTT0001XS	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Real Trachealtuben nasal 4061961A2ARTT0002XU	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Endotrachealtuben mit Cuff 4061961A2AETT002FP	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Spiraltuben Endotracheal mit Cuff 4061961A2ASTT0001YB	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Spiraltuben Endotracheal ohne Cuff 4061961A2ASTT0002YD	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Spiraltuben Endotracheal mit Cuff 4061961A2ASTT0003YF	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tubuswechsler 4061961A2ATW0001F4	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Laryngektomietubus 4061961A2ATK0001AY	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Real Trachealtuben oral 4061961A2ARTT0003XW	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Real Trachealtuben nasal 4061961A2ARTT0004XY	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter für Tracheostomie 4061961A2AAK000ZL	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Absaugkatheter Atemtrakt mit Saugregulierung 4061961A2AAK00023B	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter Atemtrakt ohne Saugregulierung 4061961A2AAK00039J	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugatheter 4061961A2AAK00063K	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter 4061961A2AAK00053H	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter 4061961A2AAK00043F	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter Bronchoskop ohne Saugregulierung 4061961A2AAK00033D	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Absaugkatheter 4061961A2AAK00083P	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter für Tracheostomie mit Saugregulierung 4061961A2AAK00103A	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugkatheter 4061961A2AAK00093R	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffkatheter mit Kompresse 4061961A2ASK0002AM	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffverbindungsschlauch 4061961A2ASK0003AP	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffkatheter ohne Kompresse 4061961A2ASK0007AX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Sauerstoffbrille 4061961A2ASK0004AR	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffkatheter mit Kompresse 4061961A2ASK0005AT	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffkatheter 4061961A2ASK0008AZ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffverbindungsschlauch 4061961A2ASK0009B3	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffverbindungsschlauch 4061961A2ASK0001AK	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Sauerstoffverbindungsschlauch 4061961A2ASK0006AV	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Bronchial Doppellumen Tubus, rechts 4061961A2ABDLT001MP	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Bronchial Doppellumen Tubus, rechts 4061961A2ABDLT004MV	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Bronchial Doppellumen Tubus, links 4061961A2ABDLT002MR	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Bronchial Doppellumen Tubus, links 4061961A2ABDLT006MZ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
BDLT Zubehör 4061961A2ABDLT003MT	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
BDLT Zubehör 4061961A2ABDLT005MX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Bronchusblocker 4061961A2ABB0001YG	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Zubehör Bronchusblocker Winkelstück 4061961A2ABB0002YJ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Spiraltubus 4061961A2ABT000385HE	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugschlauch 4061961C2ASGK003GF	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugschlauch 4061961C2ASGK006GM	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugschlauch bulk unsteril 4061961C2ASGK002GD	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Absaugsatz bulk unsteril 4061961C2AAS00037K	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugschlauch bulk unsteril 4061961C2ASGK005GK	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugsatz 4061961C2AAS00017F	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugkanüle unsteril 4061961C2ASGK008GR	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugkanülen und -rohre 4061961C2ASGK001GB	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Saugkanülen und -rohre AUT4061961C2ASGK007GP	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Saugkanülen mit Handgriff 4061961C2ASGK004GH	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Wundrandschutzfolie 4061961D2AWS0001H4	**1189DE414210525A 1189GB414210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Duodenalsonde, PVC, ohne x-ray 4061961G2aDS0002RX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Duodenalsonde 4061961G2aDS0005S5	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Duodenalsonde, PVC, mit x-ray 4061961G2ADS0003BN	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Duodenalsonde, PUR, mit x-ray 4061961G2ADS0004BQ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Magensonden und -schläuche PVC 4061961G2AMS0001F7	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Magensonden und -schläuche PUR 4061961G2AMS0002F9	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Magensonden und -schläuche PVC, x-ray 4061961G2AMS0003FB	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Magensonden und -schläuche, unsteril 4061961G2AMS0004FD	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nährsonde PVC, x-ray 4061961G2ANS0002FN	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nährsonde PUR, x-ray 4061961G2ANS0001FL	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Nährsonde 4061961G2ANS0003FQ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Ösophaguskatheter 4061961G2AOE0001B7	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Redonnadeln 4061961R2ADK0002GR	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagen unsteril 4061961R2ADK0003GT	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagen 4061961R2ADK0004GV	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagen 4061961R2ADK0010GQ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Drainagen 4061961R2ADK0001GP	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagesysteme mit Redonflasche 4061961R2ADK0011GS	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagesysteme mit Drainagebeutel 4061961R2ADK0012GU	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagesysteme 4061961R2ADK0008H5	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagesysteme 4061961R2ADK0005GX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Seldinger Pleura Drainage 4061961R2APS0002QD	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Pleura Drainage 4061961R2APS0001QB	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Thorax Drainage mit Trokar 4061961R2ATD0002LU	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Thorax Drainage 4061961R2ATD0001LS	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagen 4061961R2ADK0007H3	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Hyperthermiekatheter 4061961U2AHTK001V9	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Couvelairespitze und Ballon 4061961U2ABK0002J4	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Blasenkatheter mit Dufourspitze und Ballon 4061961U2ABK0003J6	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nephrostomy Punktionsnadel 4061961U2ADT0001MX	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Dilatator 4061961U2BNSK006Y7	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Ureterkatheter und -splinte Mono J 4061961U2AUK0003RV	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Ureterkatheter und -splinte Mono J PVC 4061961U2AUK0006S3	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Ureterkatheter und -splinte Mono J mit Olivspitze 4061961U2AUK0005RZ	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Ureterkatheter 4061961U2AUK0001RR	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Absaugsatz 4061961C2AAS00047M	**1189DE410200616 1189GB410200616 CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Wechselmandrin, Obturator Tracheostomietuben 4061961A1SET0003H3	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Wechselmandrin, Obturator 4061961A1SET0001GX	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Wechselmandrin, Obturator 4061961A1SET0002GZ	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Wechselmandrin, Obturator, unsteril 4061961A1U00001GZ3V	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Nasopharyngeal Tuben 4061961A1SNPT001SV	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nasopharyngeal Tuben 4061961A1SNPT002SX	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheal Saugset 4061961A1STS00001WD	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheal Saugset 4061961A1STS00002WF	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Tracheal Saugset 4061961A1STS00003WH	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
BAL-Katheter 4061961A1SBAL001F4	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Abdecktuch 4061961D1SAT0001HG	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Injektionskatheter 4061961D2AIK00018N	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Darmrohr 4061961G1SDR0002L8	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Darmrohr 4061961G1SDR0001L6	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Darmrohr 4061961G1DR000046Q	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Darmrohr Pädiatrie 4061961G1DR000066U	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Darmrohr 4061961G1DR000056S	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Rektalsonde 4061961G1SRS0001S7	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Urodynamik Katheter 4061961G1SCK0001HC	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Verbindungsschauch für urodynamischen Messkatheter 4061961G1SCK0002HE	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Cystoskopie-Set 4061961G1SCS0001L4	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Biopsie-Zubehör 4061961K1SBZ0001QY	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Schläuche und Schlauchabschnitte, steril 4061961K1SSA0001PA	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Schläuche und Schlauchabschnitte, steril 4061961K1SSA0003PE	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Komponenten für Medizinprodukte steril 4061961K1SK00001EJ	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Komponenten für Medizinprodukte steril 4061961K1SK00002EL	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Infusionsleitungen 4061961K2AIL0001E2	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagebeutel mit Ablass 4061961K1SDB0001HJ	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Drainagebeutel ohne Ablass 4061961K1SDB0002HL	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Urinbeutel 4061961K1SUB0001QF	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Zubehör Redon-Verbindungs-schlauch 4061961K1SRZB0001F6	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainageflaschen mit Verbindungsschlauch 4061961K1SRZB0002F8	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainageflaschen steril 4061961K1SRZB0003FA	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Urinbeutel 4061961K1SUB0002QH	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Urinbeutel Zubehör 4061961K1SSK0003SU	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Schleimsauger 4061961P1SSLS001679S	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Schleimsauger 4061961P1SSLS00269	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Nabelschnurklemme 4061961P1SNSK0014T	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Drainagen Zubehör Fixierset 4061961R2ADK0009H7	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Frauenkatheter hydrophil 4061961U1SFK0001UM	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Frauenkatheter 4061961U1SFK0005UV	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Frauenkatheter 4061961U1SFK0002UP	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Frauenkatheter 4061961U1SFK0006UX	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Frauenkatheter 4061961U1SFK0003UR	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Frauenkatheter 4061961U1SFK0004UT	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Tiemannspitze 4061961U1STK00012E	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Blasenkatheter mit Tiemannspitze 4061961U1STK00072S	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Olivspitze 4061961U1STK00032J	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Tiemannspitze 4061961U1STK00042L	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Tiemannspitze 4061961U1STK00052N	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Tiemannspitze 4061961U1STK00062Q	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Nelatonspitze 4061961U1SNK0001XV	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Blasenkatheter mit Nelatonspitze 4061961U1SNK0007Y9	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Nelatonspitze 4061961U1SNK0006Y7	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Nelatonspitze 4061961U1SNK0005Y5	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Nelatonspitze 4061961U1SNK0004Y3	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Blasenkatheter mit Nelatonspitze hydrophil 4061961U1SNK0003XZ	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028
Pusher Ureterkatheter steril 4061961U1SUK00012T	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding	☐ 31 December 2027 ☒ 31 December 2028

		substitute device under MDR	
Komponenten für Medizinprodukte steril 4061961K1SK00003EN	**1189DE415210525A 1189GB415210525A CE0482**	☒ N/A or ☐ Identification of the corresponding substitute device under MDR	☐ 31 December 2027 ☒ 31 December 2028

MED CERT®

Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

MEDICOPLAST International GmbH
Heusweilerstr. 100
66557 Illingen
Germany

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: **2020-06-16**
Expiry date: **2024-05-27**

Report No.: 1189FS19F
Process No.: QS – 1189
Certificate No.: 1189GB410200616

Hamburg, 2020-06-16

MEDCERT Certification Body
(Dr. Andreas Schich)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

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Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1189
Certificate No.: 1189GB410200616

List of products / product categories included in the scope of certificate

- **Urine drainage catheters**
- **Drainage catheters**
- **Injection catheter**
- **Feeding tubes**
- **Infusion tubes**
- **Suction sets**
- **Suction catheters**
- **Suction cannulas**
- **Suction mucus extractor**
- **Salivary gland catheter**
- **Bronchial tubes and accessories**
- **Tracheal tubes and accessories**
- **Tracheas cannulas and accessories**
- **Coniotomy set**
- **Oxygen catheter**
- **Oxygen tubes**
- **Redon systems and accessories**
- **Redon drainages**
- **Thorax catheter and accessories**
- **Jet catheter and accessories**
- **Endobronchial blocker**
- **Lavage bag sets**

– End of list –

This appendix is integral part of the above-referenced certificate.
The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Benannt durch/Designated by
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www.zlg.de
ZLG-BS-237.10.15

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Certification. Medical Only.

EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

MEDICOPLAST International GmbH
Heusweilerstr. 100
66557 Illingen
Germany

has introduced, applies and maintains a quality assurance system
for the aspects of manufacture concerned with securing and maintaining sterile conditions

for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

Effective date: **2021-05-25**
Expiry date: **2024-05-27**

Report No.: 1189FS19F
Process No.: QS – 1189
Certificate No.: 1189GB415210525A

Hamburg, 2021-05-25

MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

MEDCERT Identification Number: 0482

MED CERT®

Certification. Medical Only.

Appendix of EC Certificate of Conformity

Process No.: QS – 1189
Certificate No.: 1189GB415210525A

List of products / product categories included in the scope of certificate

- **Female-catheters**
- **Nelaton-catheters**
- **Tiemann-catheters**
- **Atraumatische Katheter**
- **Drainage bagy**
- **Rectal tubes**
- **Suction sets**
- **Suction catheters**
- **Suction cannulas**
- **Suction mucus extractor**
- **Tubes and accessoeries**
  - **Tube sections**
  - **Clamps**
  - **Connectors**
  - **Valves**
- **Tracheal tubes and accessories**
- **Tracheal cannulas and accessories**
- **Cord clamps**
- **Redon systems and accessories**
- **Redon drainages and accessories**
- **Jet catheter and accessories**
- **Biopsy attachment (needle guide sleeve)**
- **Sterile covers**

– End of list –

Imposta di bollo assolta

Ministero della Salute

EX DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
UFFICIO 3

DGDMF/3/P/I.5.1.e.1/2024/240

VISTO il Decreto Legislativo 46/1997;
HAVING REGARD *to the Legislative Decree 46/1997;*
VISTO il Decreto Legislativo 2022/137;
HAVING REGARD *to the Legislative Decree 2022/137;*
VISTO l'articolo 120 par. 3 del Regolamento UE 2017/745 relativo alle disposizioni transitorie in materia di libera circolazione e immissione in commercio dei dispositivi medici marcati CE ai sensi della Direttiva 93/42/CEE;
HAVING REGARD *to article 120 par. 3 of the EU Regulation 2017/745 related to transitional provisions on the free movement and placing on the market of medical devices marked CE pursuant to Directive 93/42/CEE;*
VISTA la Dichiarazione di Conformità CE relativa ai dispositive medici citati di seguito;
HAVING REGARD *the Declaration of Conformity CE concerning the medical device/s mentioned below;*
VISTA la Dichiarazione del fabbricante in relazione al Regolamento (UE) 2023/607 che modifica il Regolamento (UE) 2017/745 per quanto riguarda le disposizioni transitorie per alcuni dispositivi medici;
HAVING REGARD *the Manufacturer's Declaration in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices;*
VISTA la richiesta rif. 11601 -A- 12/02/2024, presentata dalla Società **MEDITALIA SAS** con sede legale in Via Saline, 75/A – 90149 Palermo, Italia, P.IVA N° 03531000820;
HAVING REGARD *to the request ref. 11601 -A- 12/02/2024, submitted by the Company* ***MEDITALIA SAS*** *with registered office in Via Saline, 75/A – 90149 Palermo, Italy, VAT N° 03531000820;*
VISTO che la Società ha pagato le quote previste dal Decreto Ministeriale 6 agosto 2021;
HAVING REGARD *the Company paid the fees required by Ministerial Decree August 6, 2021;*
VISTI gli atti ufficiali;
HAVING REGARD *to the official deeds:*

SI ATTESTA
IT IS ATTESTED

che, la Società **MEDITALIA SAS** con sede legale in Via Saline, 75/A – 90149 Palermo, Italia, è il fabbricante e ha marcato CE come dispositivi medici, secondo le modalità previste dalla Direttiva 93/42/CEE ai sensi dell'art. 120 par. 3 del Regolamento UE 2017/745, i seguenti dispositivi medici:
that, the Company ***MEDITALIA SAS*** *with registered office in Via Saline, 75/A – 90149 Palermo, Italy, is the manufacturer and has marked CE as medical devices, according to the procedures provided by the Directive 93/42/CEE pursuant to art. 120 par. 3 of EU Regulation 2017/745, the following medical devices:*

Dispositivo/ *Device*	**Codice**
CLIP PER EMOSTASI ENDOSCOPICA CON APPLICATORE UTILIZZABILI CON DUE ENDOSCOPI PER TRATTAMENTO PERFORAZIONI ED EMORRAGIE POST POLIPECTOMIA *ENDOSCOPIC HEMOSTATIC CLIP WITH APPLICATOR, USABLE WITH DUODENOSCOPE, AND FOR POST POLYPECTOMY PERFORATION AND BLEEDING TREATMENT*	MED-XXX-CLP
CESTELLI PER ESTRAZIONE *STONE EXTRACTION BASKETS*	MED-XXX-BAS
FILI GUIDA PER GASTROENTEROLOGIA *GASTROENTEROLOGY GUIDE WIRES*	MED-XXX-WIR
PINZE PER BIOPSIA *BIOPSY FORCEPS*	MED-XXX-FOR
PINZE PER RECUPERO CORPI ESTRANEI *RETRIEVAL FORCEPS*	MED-XXX-RET
ANSE PER POLIPECTOMIA E/O RECUPERO *POLIPECTOMY AND/OR RETRIEVAL SNARES*	MED-XXX-SNA MED-XXX-NET MED-XXX-MUL MED-XXX-MUC
ANSA PER POLIPECTOMIA A FREDDO/*DISPOSABLE POLYPECTOMY COLD SNARE*	MED-XXX-COLD
CATETERI A PALLONCINO PER ESTRAZIONE CALCOLI *DISPOSABLE STONE EXTRACTION BALLOON*	MED-2XX-EXT MED4XX-EXT
AGHI PER INIEZIONE ENDOSCOPICA *ENDOSCOPIC INJECTION NEEDLES*	MED-XXX-INJ
VALVOLE BIOPTICHE *BIOPSY VALVES*	V-OLY/V-PENTAX
PINZA MULTIFUNZIONE PER BIOPSIA E RESEZIONE POLIPI DIMINUITIVI A FREDDO E MULTIPRELIEVO / *MULTIFUCTIONAL FORCEPS FOR BIOPSIES AND COLD RESECTION OF DIMINUITIVE POLYPS AND MULTIBITE*	MED-XXX-LEV

I prodotti sopra citati, ai sensi dell'articolo 4 della Direttiva 93/42/CEE e dell'articolo 120 par. 3 del Regolamento 2017/745, possono circolare liberamente ed essere immessi sul mercato in Italia e in tutta l'Unione Europea.

The above mentioned product, according to the article 4 of Directive 93/42/CEE pursuant to article 120 par. 3 of Regulation 2017/745, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è stato emesso in versione originale su richiesta del fabbricante al fine di esportare dispositivi medici nei **Paesi al di fuori dell'Unione Europea**.

*This document has been issued in original version upon request of the manufacturer in order to export medical devices to **Countries outside European Union**.*

Il Dirigente Sanitario
ıger
ella

RM

Meditalia®

Manufacturer's Declaration

In relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MEDITALIA S.A.S. IMPORT/EXPORT DI PEZZINO SEBASTIANA
Manufacturer address and contact details	Via Saline, 75/a, Palermo, CAP 90149 + 39 091 6841193 mednatio@meditaliasas.it
Single Registration Number (SRN)	IT-MF-000028625

Notified body name	ICIM □ See attached schedule
Notified body number	NB 0425 □ See attached schedule
Directive Certificate number to which this confirmation is made	0425-med-002649-02 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	26-05-2024 □ See attached schedule
End date of extended validity/transition period	31-12-2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

Direzione Generale, Amministrazione: Via Saline, 75/A – 90149 Palermo (Italy)
Tel. +39 091 6841193 • Fax +39 091 6893002 • E-mail: mednatio@meditaliasas.it • medinter@meditaliasas.it •
PEC: meditaliasas@legalmail.it
SITO WEB: www.meditaliasas.it
C.F./P.I. 03531000820 • C.C.I.A.A. 6992/00044 • ISCR. TRIB. 30264 • LIC.IMP.EXP.M.551945
Azienda Certificata ISO 9001 Cert. N. 6049 e ISO 13485 Cert. N. 6050

- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*[1]
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above or in the attached schedule

- Directive Certificate covering the listed device was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

  Expired *after* 20 March 2023:

  Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or their substitutes and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name MEDITALIA S.A.S. IMPORT/EXPORT DI PEZZINO SEBASTIANA

Location & Date Palermo 2024-08-05

Signature, Print Name, Title PEZZINO SEBASTIANA

Contact Details (at least email) mednatio@meditaliasas.it

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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C.F./P.I. 03531000820 • C.C.I.A.A. 6992/00044 • ISCR. TRIB. 30264 •LIC.IMP.EXP.M.551945

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
MED-XXX-CLP endoscopic hemostatic clip with applicator, usable with duodenoscope and for all hemostasis and bleeding treatments (Perforations), post polypectomy and ERCP procedures, bleeding ulcers and colon diverticulitis	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-BAS Stone extraction baskets	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-WIR Gastroenterology guide wires	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-FOR Biopsy forceps	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	

[2] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Direzione Generale, Amministrazione: Via Saline, 75/A – 90149 Palermo (Italy)
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PEC: meditaliasas@legalmail.it
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C.F./P.I. 03531000820 • C.C.I.A.A. 6992/00044 • ISCR. TRIB. 30264 •LIC.IMP.EXP.M.551945

MED-XXX-LEV Multifunctional forceps for biopsies and cold resection of diminutive polyps and multibite	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-RET Retrieval forceps	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-SNA/MED-XXX-NET MED-XXX-MUL/MED-XXX-MUC MED-XXX-COLD Polyoectomy and/or retrieval snares	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-EXT Disposable stone extraction ballon	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
MED-XXX-INJ Endoscopic injection needles used with duodenoscope for ERCP procedures	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	
V-OLY / V-PENTAX Biopsy valves	0425-MED-002649-02	26-05-2024	ICIM S.p.A Identification number 0425	ICIM S.p.A Identification number 0425	31-12-2028	

Direzione Generale, Amministrazione: Via Saline, 75/A – 90149 Palermo (Italy)
Tel. +39 091 6841193 • Fax +39 091 6893002 • E-mail: mednatio@meditaliasas.it • medinter@meditaliasas.it •
PEC: meditaliasas@legalmail.it
SITO WEB: www.meditaliasas.it
C.F./P.I. 03531000820 • C.C.I.A.A. 6992/00044 • ISCR. TRIB. 30264 •LIC.IMP.EXP.M.551945

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

CERTIFICATO N. **ICIM-9001-006049-04**

CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

MEDITALIA S.A.S.IMPORT/EXPORT DI PEZZINO SEBASTIANA

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Saline 75/a 90149 Palermo PA IT - Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29 - 14

Gestione della progettazione, della produzione, immissione sul mercato e commercializzazione di dispositivi per gastroenterologia.

Management of design, manufacturing, place on the market and trading of gastroenterology devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
02/04/2012	/	01/04/2027

Vincenzo Delacqua

Rappresentante Direzione / *Management Representative*

ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)

www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0004

CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.

0449CM_05_IT

Building trust together.

Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

MEDITALIA S.A.S.IMPORT/EXPORT DI PEZZINO SEBASTIANA

Via Saline 75/a 90149 Palermo PA IT - Italia

has implemented and maintains a/an

Quality Management System

for the following scope:

Management of design, manufacturing, place on the market and trading of gastroenterology devices.

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on:	**2024-03-28**
First issued on:	**2012-04-02**
Expires on:	**2027-04-01**

Registration Number:

IT-82925 ICIM-9001-006049-04

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

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* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_05_EN

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

CERTIFICATO N. **ICIM-13485-006050-05**

CERTIFICATE No.

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

MEDITALIA S.A.S.IMPORT/EXPORT DI PEZZINO SEBASTIANA

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Via Saline 75/a 90149 Palermo PA IT - Italia

È CONFORME ALLA NORMA

UNI CEI EN ISO 13485:2021

IS IN COMPLIANCE WITH THE STANDARD

ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Gestione della progettazione, della produzione, immissione sul mercato e commercializzazione di dispositivi per gastroenterologia.

Management of design, manufacturing, place on the market and trading of gastroenterology devices.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
02/04/2012	02/04/2024	01/04/2027

Vincenzo Delacqua
Rappresentante Direzione / *Management Representative*
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0004

CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.

0860CM_06_IT

IQNET

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Certificate

CISQ/ICIM S.P.A. has issued an IQNET recognized certificate that the organization:

MEDITALIA S.A.S.IMPORT/EXPORT DI PEZZINO SEBASTIANA

Via Saline 75/a 90149 Palermo PA IT - Italia

has implemented and maintains a/an

Quality Management System

for the following scope:

Management of design, manufacturing, place on the market and trading of gastroenterology devices.

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on:	**2024-04-02**
First issued on:	**2012-04-02**
Expires on:	**2027-04-01**

Registration Number:

IT-82926 ICIM-13485-006050-05

President of IQNET

President of CISQ

CISQ

This attestation is directly linked to the IQNET Member's original certificate and shall not be used as a stand-alone document.

IQNET Members*:

AENOR Spain **AFNOR Certification** France **APCER** Portugal **CCC** Cyprus **CISQ** Italy **CQC** China **CQM** China **CQS** Czech Republic **Cro Cert** Croatia **DQS Holding GmbH** Germany **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Turkey **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

0774CM_05_EN

S E R T I F I K A T A S

Visiška kokybės užtikrinimo sistema

Medicinos prietaisų direktyvos 93/42/ESC II priedas (išskyrus 4 skirsnį)

Įmonės pavadinimas

Kompanijos adresas

Gamybos svetainė

Susijusios direktyvos ir priedas produktas

Sertifikato numerio ataskaitos numeris

Pirminio vertinimo data Registracijos data

: Technocast Otomotiv San ve Tic. A.Ş.

: Organizuoti Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Kad. No:12 Çerkezköy TEKIRDAG / TURKIJA

: Technocast Otomotiv Sanayi ir Ticaret A.Ş Medikal Şubesi

Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Kad. No:26 Çerkezköy TEKiRDAG / TURKIJA

: Medicinos prietaisų direktyva 93/42/EEB – II priedas (išskyrus 4 skirsnį)

- Ištraukimo krepšelis - Ila klasė - Sterilus
- Griebimo žnyplės - Ila klasė - Sterilus
- Sfinkterotomas - Ilb klasė - Sterilus
- Polipektomijos kilpai - Ilb klasė - Sterilus
- E.R.C.P kateteris - klasė yra - sterilus
- Akmens ištraukimo balionas - Ila klasė - Sterilus
- Tulžies stentas - Ila klasė - Sterilus

: 37141, 37141, 58039, 38827, 16429, 46715, 10696

: M.2016.106.7002

: MD.3157.YB

: 2016-07-27

: 2016-10-04

Pakartotinio sertifikavimo vertinimo data: 2020-03-04

UDEM lnterri ona îfication

Pakartotinio išleidimo data / Nėra peržiūros datos / Nr

: 2020-06-10/01

Audito mokymas ntre Pramonė

ir Trade Inc. Co.

Galiojimo laikas: 2024-05-27

07/05/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER

CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0180/P1/R1

Subject: 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.

To whom it may concern,

This letteris the official document of UDEM A.Ş., a Notified Body (NB) designated in accordance with Regulation (EU) 2017/745 (MDR) and identified in NANDO with the number 2292, in accordance with the first subparagraph of Chapter 4.3 of Annex VII of the MDR and confirms that UDEM A.Ş. has received an application and has signed a written contract in accordance with the second subparagraph of Chapter 4.3 of Annex VII to the MDR with the following manufacturer:

Company Name:	TECHNOCAST OTOMOTİV SAN VE TİC. A.Ş.
Company Address:	**CENTER:** ÇERKEZKÖY ORGANİZE SANAYİ BÖLGESİ GAZİ OSMAN PAŞA MAH.6. CADDE NO:12 ÇERKEZKÖY/TEKİRDAĞ **MANUFACTURING ADDRESS:** TECHNOCAST OTOMOTİV SANAYİ VE TİCARET A.Ş MEDİKAL ŞUBESİ, ÇERKEZKÖY ORGANİZE SANAYİ BÖLGESİ GAZİ OSMAN PAŞA MAH.6.CADDE NO:26 ÇERKEZKÖY/TEKİRDAĞ
SRN Number (if any):	TR-MF-000030603

The devices covered by the above-mentioned official application and written contract are defined in the tables below. Table 1 describes the devices for which an MDR application has been received, a written contract has been made and UDEM A.Ş. is also responsible for the appropriate surveillance of the relevant devices within the scope of the 93/42/EEC Medical Device Directive (MDD). Table 2 identifies devices for which an MDR application has been received and a written contract has been concluded, but for which UDEM A.Ş. has not yet taken appropriate surveillance responsibility for the relevant devices under the MDD.

For devices covered by certificates issued under the MDD which expire after 26 May 2021 and before 20 March 2023 without withdrawal, this letter also confirms that the manufacturer has provided evidence that the competent authority of the Member State under the MDR up to the date of expiry of the MDD certificate has granted an exception or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of the MDR or Article 97(1) of the MDR for the devices concerned until 20 March 2023.

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:

III klasės priemonių CE pratęsta iki 2026 06 26

- 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)

IIb klasės priemonių (skirtų odontologijai) CE pratęsta iki 2027 12 31

- 31 December 2028 for class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in a sterile condition or with a measurement function,

IIb, IIa klasės priemonių CE pratęsta iki 2027 12 31

- 31 December 2028 for devices for which the conformity assessment procedure in accordance with Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure in accordance with the MDR requires the involvement of a notified body.

UDEM A.Ş. General Manager Name-Surname:	MUSTAFA MEMİŞOĞLU
Date:	07.05.2024
Stamp-Signature:	

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Ümitköy Çankaya/Ankara
0(312) 443 03 90
mdr@udem.com.tr

Table-1 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

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
BILIARY STENT SET	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2021.106.14330 Certificate 1: 2292
BILIARY STENT	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
SPHINCTEROTOME	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
EXTRACTION BASKET	Class IIa	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292
STONE EXTRACTION BALLOON	Class IIa	N/A	Certificate 1: M.2016.106.7002 Certificate 1: 2292

Tablo-2 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Not Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

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
N/A	N/A	N/A	N/A

CONTRACT CONFIRMATION LETTER REVISION HISTORY

Date	Contract Confirmation Letter Revision Number	Revision Explanation
06/05/2024	CL.CONTRACT.UDEM.0180/P1	Preparation of contract confirmation letter
07/05/2024	CL.CONTRACT.UDEM.0180/P1/R1	Adding the manufacturing location address

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Ümitköy Çankaya/Ankara
0(312) 443 03 90
mdr@udem.com.tr

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Technocast Otomotiv San ve Tic. A.Ş.
Company Address	: Organize Sanayi Bölgesi Gazi Osman Paşa Mah. 6. Cad. No:12 Çerkezköy TEKİRDAĞ / TURKEY
Manufacturing Site	: Technocast Otomotiv Sanayi ve Ticaret A.Ş Medikal Şubesi Çerkezköy Organize San. Bölg. Gazi Osman Paşa Mah. 6. Cad. No:26 Çerkezköy TEKİRDAĞ / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Extraction Basket - Class IIa - Sterile - Grasping Forceps - Class IIa - Sterile - Sphincterotome - Class IIb - Sterile - Polypectomy Snare - Class IIb - Sterile - E.R.C.P Catheter - Class Is - Sterile - Stone Extraction Balloon - Class IIa - Sterile - Biliary Stent - Class IIa - Sterile
GMDN	: 37141, 37141, 58039, 38827, 16429, 46715, 10696
Certificate Number	: M.2016.106.7002
Report Number	: MD.3157.YB
Initial Assessment Date	: 27.07.2016
Registration Date	: 04.10.2016
Recertification Assessment Date	: 04.03.2020
Reissue Date / No	: 10.06.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073283 0047 Rev. 01

Manufacturer

Ningbo Greetmed Medical Instruments Co., Ltd.
16F-1, Building 1
No. 98 Chuangyuan Road, Hi-Tech Zone
315042 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

General non-active, non-implantable medical devices

Non-active devices for anaesthesia, emergency and intensive care

Non-active devices for injection, infusion, transfusion and dialysis

Non-active instruments

Bandages and wound dressings

Medical Gloves

(For detailed information please see attachment)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH19299EXT01

Valid from: 2020-03-16
Valid until: 2024-05-26

Date, 2020-03-16

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073283 0047 Rev. 01

Non-woven Swab, Gauze Swab, Elastic Bandage,
Urine Bag, Umbilical Cord Clamp, First-Aid-Kit ,
Sterile Hemostasis Adhesive Dressing Series
(Sterile Wound Plaster, Liquid Transfusion Plaster
and Adhesive Dressing), Rectal Tube, Vaginal Speculum,
Oropharyngeal Airway, Surgical Gowns, Surgical Brush,
Absorbent Cotton Balls, Eye Pad, Dressing Kits,
External Male Catheter, Gynecological Sets,
Cervical Brushes, Nasal Speculas, Irrigation Syringes,
Alcohol Swabs, Disposable Colostomy Bags,
Nasopharyngeal Airway, Wooden Tongue Depressors,
Male/Female Swab, Gauze Roll, Gauze Bandage,
Non-woven Face Masks,
Sterile Examination Gloves,
Surgical Drapes, Cotton Tipped Applicators, Gauze Ball,
Wooden Ayre Spatulas,
Disposable Plastic Forceps, Disposable Anoscope,
Surgical Set, Medicine Cup, I.D. Bracelets,
Alcohol Swabsticks, Disposable Infusion Connection Tube,
Spigot, Urine Bag Infant, Enema Bag, Sterile Vaginal Applicator,
Transportation Swabs with Medium, Disposable Anesthesia Laryngoscope

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CE SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V
(Prietaisai I klasėje steriliose sąlygose, sterilizacijos sistemos ar procedūriniai rinkiniai)

Nr. G2S 073283 0047 Rev. 01

Gamintojas:	**Ningbo Greetmed Medical Instruments Co., Ltd.** 16F-1, Building 1 No. 98 Chuangyuan Road, Hi-tech Zone 315042 Ningbo, Zhejiang Province KINIJOS LIAUDIES RESPUBLIKA
Produkto kategorija(os):	**Neaktyvūs, neimplantuojami medicinos prietaisai** **Neaktyvūs prietaisai anestezijai, greitajai pagalbai ir intensyviajai terapijai** **Neaktyvūs prietaisai injekcijai, infuzijai, transfuzijai ir dializei** **Neaktyvūs instrumentai** **Bintai ir žaizdų tvarsčiai** **Medicininės pirštinės** **(detali informacija pateikta priede)**

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH patvirtina, kad paminėtasis gamintojas įdiegė kokybės užtikrinimo sistemą atitinkamų prietaisų / prietaisų kategorijų gamybai ir galutiniam patikrinimui pagal medicinos prietaisų direktyvos 93/42/EEB V Priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. Taip pat žr. kitame puslapyje.

Protokolo Nr.	SH19299EXT01
Galioja nuo:	2020-03-16
Galioja iki:	2024-05-26

Data, 2020-03-16

/parašas/
Christoph Dicks
Sertifikavimo/Notifikuotos Įstaigos vadovas

TÜV SÜD Product Service GmbH yra Notifikuota Įstaiga, identifikacijos Nr. 0123.

CE SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V
(Prietaisai I klasėje steriliose sąlygose, sterilizacijos sistemos ar procedūriniai rinkiniai)

Nr. G2S 073283 0047 Rev. 01

Neaustinis Tamponas, Marlinis Tamponas, Elastinis Tvarstis,
Šlapimo Surinkėjas, Umbilikalinis Spaustukas, Pirmos Pagalbos Rinkinys,
Sterilių Lipniu Hemostatinių Tvarsčių Serijos,
(Sterilus Žaizdų Pleistras, Skystas Transfuzinis Pleistras, Lipnus Tvarstis)
Rektalinis Vamzdelis, Vaginalinė Spekulė,
Orofaringinis Vamzdelis, Chirurginiai Chalatai, Chirurginiai Šepečiai,
Sugeriantys Medvilnės Tamponai, Akių Tamponėliai, Tvarsliavos Rinkiniai,
Išoriniai Vyriškis Kateteriai, Ginekologiniai Rinkiniai,
Ginekologiniai Šepetėliai, Nazalinės Spekulės, Irigaciniai Švirkštai,
Injekcinės Servetėlės, Kolostomijos Maišeliai,
Nazofaringiniai Vamzdeliai, Medinės Liežuvio Mentelės,
Vyriškas/Moteriškas Tamponėlis, Marlės Ritinys, Marlinis Bintas,
Neaustinės Kaukės,
Sterilios Apžiūros Pirštinės,
Chirurginiai Apdangalai, Aplikatoriai Su Medvilne, Marlės tamponai,
Medinės Ginekologinės Mentelės,
Vienkartiniai Plastikiniai Pincetai, Vienkartinis Anoskopas,
Chirurginis Rinkinys, Medicinis puodelis, Apyrankės,
Pagaliukai su alkoholiu, Vienkartiniai Infuzijų Prailginimo Vamzdeliai,
Kamšteliai, Pediatriniai Šlapimo Surinkėjai, Klizmavimo Maišelis, Sterilus Vaginalinis Aplikatorius,
Medium Transportavimo Tepinėliai, Vienkartinis anestezinis laringoskopas

TÜV SÜD Product Service GmbH yra Notifikuota Įstaiga, identifikacijos Nr. 0123.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 073283 0046 Rev. 01

Manufacturer:

Ningbo Greetmed Medical Instruments Co., Ltd.
16F-1, Building 1
No. 98 Chuangyuan Road, Hi-Tech Zone
315042 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Non-active devices for anaesthesia, emergency and intensive care
Non-active devices for injection, infusion, transfusion and dialysis
Non-active instruments
Bandages and wound dressings
Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
Monitoring devices of vital physiological parameters
Medical Gloves
(For detailed information please see attachment)

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.: SH19299EXT01

Valid from: 2020-03-16
Valid until: 2024-05-26

Date, 2020-03-16

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD 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 073283 0046 Rev. 01

Tracheal Tubes, Surgical Gloves,
Electronic Sphygmomanometers, Digital Thermometers,
Infra-red Ear Thermometers, Infra-red Forehead Thermometers,
Disposable Infusion Sets, Disposable Syringe Sets,
Disposable Blood Transfusion Sets,
Disposable Scalp Vein Sets, Oxygen Masks, Aerosol Masks,
Nasal Oxygen Cannula, Non-Rebreath Masks,
Disposable Surgical Blades, Sterile Blood Lancets,
Suction Catheters, Feeding Tubes, Stomach Tubes,
Connecting Tubes with Yankauer Handle, Nelaton Catheters,
Reinforced Endotracheal Tubes, Laryngeal Mask,
Mucus Extractor, Wound Drainage Reservoir,
Three-way Stopcocks, Heparin Caps, I.V. Cannula,
Insulin Syringe, Infusion Set with Burette,
Hypodermic Needle, Closed Suction Catheter,
Safety Syringes, CPR Masks,
Venturi Masks, Ultrasonic Nebulizer,
Compressor Nebulizer, Tracheostomy Mask,
Manual Resuscitators, T-Drainage Tube,
Penrose Tube, Lap Sponges, Insulin Pen Needles,
Electrocardiograph, Lubricating Jelly, Urethral Catheters,
Endotracheal Tube Introducers, Anesthetic Breathing Circuits,
Endotracheal Tubes with Evacuation Lumen,
O2+CO2 Sampling Cannulas, Humidifier Jar,
Mask Nebulizer Container, Auto-disable Syringe,
Anesthesia Mask, Resuscitation Mask,

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TÜV SÜD 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 073283 0046 Rev. 01

Nebulizers with Mouth-pieces, Oxygen Connection Tubings,

Nebulizer Set, Three-way Stopcock and Extension Tube,

Dental Needles, Disposable Vacuum Blood Collection System,

Disposable Umbilical Cord Scissors, Blood-Collecting Needles,

Heat & Moisture Exchanger Filters,

Breathing System Filters, Drainage Tubes,

Screw Cap, Combi Stopper, Enema Set

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CE SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V
(Prietaisai IIa, IIb ir III klasėje)

Nr. G2 073283 0046 Rev. 01

Gamintojas:	**Ningbo Greetmed Medical Instruments Co., Ltd.** 16F-1, No.1 Building Nr. 98 Chuangyuan ROad, Hi-Tech Zona 315042 Ningbo, Zhejiang Provincija KINIJOS LIAUDIES RESPUBLIKA
Produkto kategorija(os):	**Neaktyvūs prietaisai anestezijai, greitajai pagalbai, intensyviai priežiūrai,** **Neaktyvūs prietaisai injekcijai, infuzijai, transfuzijai ir dializei** **Neaktyvūs instrumentai** **Tvarsčiai ir žaizdų perišimai** **Kvėpavimo prietaisai, įskaitant hiperbarinius kambarius deguonies terapijai, inhaliacinei anestezijai** **Gyvybinių fiziologinių parametrų stebėsenos prietaisai** **Medicininės pirštinės** **(Detalus sąrašas priede)**

Sertifikavimo įstaiga TÜV SÜD Product Service GmbH patvirtina, kad paminėtasis gamintojas įdiegė kokybės užtikrinimo sistemą atitinkamų prietaisų / prietaisų kategorijų gamybai ir galutiniam patikrinimui pagal medicinos prietaisų direktyvos 93/42/EEB V Priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos sąlygas ir turi būti periodiškai peržiūrima. IIb ir III klasės produktams yra privalomas papildomas III priedo sertifikatas. Taip pat žr. kitame lape.

Protokolo Nr.	SH19299EXT01
Galioja nuo:	2020-03-16
Galioja iki:	2024-05-26

Data, 2020-03-16 /parašas/
Christoph Dicks
Sertifikacijos/Notifikuojančios įstaigos galva

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

CE SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V
(Prietaisai IIa, IIb ir III klasėje)

Nr. G2 073283 0046 Rev. 01

Trachėjos vamzdeliai, Chirurginės pirštinės,
Elektroninės spigmomanometrai, skaitmeniniai termometrai,
Infra-raudonieji ausies termometrai, infra-raudonieji kaktos termometrai,
Vienkartiniai infuzijos rinkiniai, vienkartiniai švirkštų rinkiniai,
Vienkartiniai kraujo transfuzijos rinkiniai,
Vienkartinės galvos venų (butterfly) rinkiniai, Deguonies kaukės, aerozolinės kaukės,
Nosies deguonies kaniulės, nereaguojančios kaukės,
Vienkartiniai chirurginiai peiliukai, sterilūs kraujo lancetai,
Atsiurbimo kateteriai, Maitinimo zondai, skrandžio zondai,
Jungiamieji vamzdeliai su Yankauer rankena, Nelaton kateteriai,
Sustiprinti endotrachėjiniai vamzdeliai, gerklų kaukės,
Atsiurbėjai su talpa, žaizdų drenažo rezervuaras,
Trijų krypčių kraneliai, heparino dangteliai, I.V. kaniulės,
Insulino švirkštai, infuzijos rinkiniai su biurete,
Hipoderminės adatos, uždaras atsiurbimo kateteris,
Saugūs švirkštai, CPR kaukės,
Venturi kaukės, ultragarsinis purkštuvas,
Kompresorius purkštuvas, Tracheostominė kaukė,
Rankinis reanimatologas, T-drenažo vamzdelis,
Penrose vamzdeliai, juosmens kempinės, insulino peno adatos,
Elektrokardiografas, lubrikuojanti želė, ureteriniai kateteriai,
Endotrachėjinių vamzdelių įvedėjai, anestetinės kvėpavimo grandinės,
Endotrachėhiniai vamzdeliai su evakuacijos spindžiu,
02+CO2 pavyzdinės kaniulės, drėkintuvo indas,
Kaukės purkštuvo konteineris, automatinio išjungimo švirkštai,
Anestezinės kaukės, gaivinimo kaukės,

CE SERTIFIKATAS

Gamybos kokybės užtikrinimo sistema

Medicinos prietaisų direktyva 93/42/EEB, Priedas V
(Prietaisai IIa, IIb ir III klasėje)

Nr. G2 073283 0046 Rev. 01

Purkštuvas su kandikliais, deguonies jungiamieji vamzdeliai,
Purkštuvų rinkinys, trijų krypčių kraneliai su prailginimo linija,
Dantų adatos, vienkartiniai vakuuminiai kraujo surinkimo maišeliai,
Vienkartiniai umbilikaliniai spaustukai, kraujo surinkimo adatos,
Šilumos ir drėgmės šilumokaičio filtrai,
Kvėpavimo sistemos filtrai, drenažo vamzdeliai,
Prisukami dangteliai, kombinuotas kamštis, klizmos rinkinys

PRODUCT LIST FOR CERTIFICATE

Issued to: Ningbo Greetmed Medical Instruments Co., Ltd.

Certificate number: 28620168227

Certificate valid from: 2024-02-22

Product List Issue Date:
22 February 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices			
Basic UDI-DI: 69586275GT064-100WT			
GT064-100 - Surgical Drape	Class I(s) T020102		2024-02-22
GT064-101 - Surgical Drape	Class I(s) T020102		2024-02-22
Basic UDI-DI: 69586275GTS029-320TB			
GT-BT-A1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-A500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-A600ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-A750ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-A800ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-A900ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B600ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B750ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B800ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-B900ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-C1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-C500ml - Urine Bag	Class I(s) A06030301		2024-02-22

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
GT-BT-C600ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-C750ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-C800ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-BT-C900ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-DC-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-DC-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-DC-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-JC-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-JC-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HA-JC-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-DC-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-DC-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-DC-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-JC-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-JC-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-HB-JC-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JA-2200ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JA-2500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JA-3000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JA-3100ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JB-2200ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JB-2500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JB-3000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-JB-3100ml - Urine Bag	Class I(s) A06030301		2024-02-22

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620168227
Product list issue date: 22 February 2024

Product	Classification and EMDN	Intended use[1]	Date Added
GT-PA-LT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-LT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-LT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-LT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-ST-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-ST-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-ST-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-ST-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-TT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-TT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-TT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PA-TT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-LT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-LT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-LT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-LT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-ST-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-ST-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-ST-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-ST-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-TT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-TT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-TT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PB-TT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620168227
Product list issue date: 22 February 2024

Product	Classification and EMDN	Intended use[1]	Date Added
GT-PC-LT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-LT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-LT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-LT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-ST-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-ST-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-ST-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-ST-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-TT-1000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-TT-1500ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-TT-2000ml - Urine Bag	Class I(s) A06030301		2024-02-22
GT-PC-TT-500ml - Urine Bag	Class I(s) A06030301		2024-02-22
Basic UDI-DI: 69586275GTS065-100T3			
GT065-100-22-12P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-22-16P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-22-8P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-33-12P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-33-16P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-33-8P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-43-8P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-44-12P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-44-16P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-44-8P - Gauze Swab	Class I(s) M020106		2024-02-22
GT065-100-48-12P - Gauze Swab	Class I(s) M020106		2024-02-22

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620168227
Product list issue date: 22 February 2024

Product	Classification and EMDN	Intended use[1]	Date Added
GT065-100-48-16P - Gauze Swab	Class I(s) M020106		2024-02-22
Basic UDI-DI: 69586275GTS070-100RR			
GT070-100-22-3P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-22-4P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-22-6P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-33-4P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-33-6P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-43-4P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-44-3P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-44-4P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
GT070-100-44-6P - Non-woven Swab	Class I(s) M0202010101		2024-02-22
Basic UDI-DI: 69586275GTS110-009Q9			
GT063-100LL - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100L - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100M - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100S - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100XL - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100XS - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100XXL - Surgical Gowns	Class I(s) T020401		2024-02-22
GT063-100XXXL - Surgical Gowns	Class I(s) T020401		2024-02-22

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620168227
Product list issue date: 22 February 2024

Product	Classification and EMDN	Intended use[1]	Date Added

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620168227
Product list issue date: 22 February 2024

EC CERTIFICATION

EU QUALITY ASSURANCE CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements - has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620168227

Revision:
00

Initial Certification Date:
22 February 2024

Date of Certification Decision:
22 February 2024

Certificate Issue Date:
22 February 2024

Certificate Expiry Date:
21 February 2029

Ningbo Greetmed Medical Instruments Co., Ltd.

16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Manufacturer SRN: CN-MF-000009634

Authorised Representative Name

MedPath GmbH

Mies-van-der-Rohe-Strasse, 8 80807 Munich, Germany

Scope:

- Sterility aspects of devices as detailed in attached product list.

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2022-603431**
	Stage 2 audit ACTY-2022-603432

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620168227

Revision:
00

Initial Certification Date:
22 February 2024

Date of Certification Decision:
22 February 2024

Certificate Issue Date:
22 February 2024

Certificate Expiry Date:
21 February 2029

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

Ningbo Greetmed Medical Instruments Co.,Ltd.
16F-1, Building 1, No.98 Chuangyuan Road,
Hi-Tech Zone, 315042 Ningbo, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

5 June 2024

Notified Body Confirmation Letter
Reference: CN00310-02

To whom it may concern,

Certificates included:
MDD EC Certificate Annex II, G2 073283 0046 Rev. 01, G2S 073283 0047 Rev. 01, NB 0123
See attached tables for details of devices.

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, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 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:

Ningbo Greetmed Medical Instruments Co.,Ltd.
16F-1, Building 1, No.98 Chuangyuan Road,
Hi-Tech Zone, 315042 Ningbo, Zhejiang Province,
PEOPLE'S REPUBLIC OF CHINA

SRN Number (if available): CN-MF-000009634

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,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

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
GT-PA-ST-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-ST-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-ST-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-ST-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-ST-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-ST-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-ST-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-ST-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-ST-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-ST-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-ST-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123

GT-PC-ST-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-LT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-LT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-LT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-LT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-LT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-LT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-LT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-LT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-LT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-LT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-LT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-LT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-TT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-TT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-TT-500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-TT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-TT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-TT-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-TT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-TT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-TT-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PA-TT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PB-TT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-PC-TT-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123

GT-HA-JC-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-JC-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HA-JC-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-JC-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HA-JC-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-JC-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HA-DC-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-DC-1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HA-DC-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-DC-1500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HA-DC-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-HB-DC-2000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JA-2200ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JB-2200ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JA-2500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JB-2500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JA-3000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JB-3000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JA-3100ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-JB-3100ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-C500ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A600ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B600ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123

GT-BT-C600ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A750ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B750ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-C750ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A800ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B800ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-C800ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A900ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B900ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-C900ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-A1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-B1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT-BT-C1000ml	Urine Bag	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-22-8P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-22-12P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-22-16P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-33-8P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-33-12P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-33-16P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-44-8P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-44-12P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-44-16P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-43-8P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-48-12P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT065-100-48-16P	Gauze Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123

GT070-100-22-3P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-22-4P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-22-6P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-33-4P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-33-6P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-44-3P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-44-4P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-44-6P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT070-100-43-4P	Non-woven Swab	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT064-100	Surgical Drape	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT064-101	Surgical Drape	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100XS	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100S	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100M	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100L	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100XL	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100XXL	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100XXXL	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100LL	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100S	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100M	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
GT063-100L	Surgical Gowns	Class Is	NA	G2S 073283 0047 Rev. 01, NB 0123
30mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
40mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
50mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123

60mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
70mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
80mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
90mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
100mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
110mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
120mm	Oropharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.2.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.3.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.3.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.4.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.4.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.5.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.5.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.6.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.6.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.7.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.7.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.8.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.8.5	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I.D.9.0	Nasopharyngeal Airway	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
60ml	Irrigation Syringes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
80ml	Irrigation Syringes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
100ml	Irrigation Syringes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
20mm	External Male Catheter	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
25mm	External Male Catheter	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
30mm	External Male Catheter	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
35mm	External Male Catheter	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123

40mm	External Male Catheter	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
1000ml	Enema Bag	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
1200ml	Enema Bag	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
1500ml	Enema Bag	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
1750ml	Enema Bag	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
2000ml	Enema Bag	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT167-101	Surgical Set	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
Child	Wooden Tongue Depressors	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
Adult	Wooden Tongue Depressors	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
S	Vaginal Speculum	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
M	Vaginal Speculum	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
L	Vaginal Speculum	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT077-300	Cotton Tipped Applicators	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT159-200	Gynecological Sets	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
I	Cervical Brushes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
J	Cervical Brushes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
K-1	Cervical Brushes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
M	Cervical Brushes	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT078-100	Surgical Brush	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT112-100	Umbilical Cord Clamp	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-100	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-200	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-300	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-301	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-302	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-303	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-304	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-305	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT095-306	Dressing Kits	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123

GT100-100	Sterile Hemostasis Adhesive Dressing Series	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT102-120	Sterile Hemostasis Adhesive Dressing Series	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
GT102-110	Sterile Hemostasis Adhesive Dressing Series	Class Is	NA	G2S 073283 0047 Rev.01, NB 0123
S	Oxygen Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
M	Oxygen Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
L	Oxygen Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
XL	Oxygen Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Nasal Oxygen Cannula	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
child	Nasal Oxygen Cannula	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
infant	Nasal Oxygen Cannula	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Neonate	Nasal Oxygen Cannula	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
2M	Oxygen Connection Tubings	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT117-300	CPR Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT117-400	CPR Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Manual Resuscitators	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
pediatric	Manual Resuscitators	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
infant	Manual Resuscitators	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
000#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
00#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
0#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
2#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
4#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6#	Anesthesia Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Anesthetic Breathing Circuits	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
child	Anesthetic Breathing Circuits	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

S	Aerosol Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
M	Aerosol Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
L	Aerosol Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
XL	Aerosol Masks	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.2.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.2.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.3.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.3.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.4.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.4.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.5.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.5.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.6.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.6.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.7.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.7.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.8.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.8.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.9.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.9.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.10.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.10.5	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
I.D.11.0	Tracheal Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
12Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
14Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

16Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
18Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20Fr	Feeding Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
12Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
14Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
16Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
18Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20Fr	Stomach Tubes	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1/4"	Connecting Tubes with Yankauer Handle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3/16"	Connecting Tubes with Yankauer Handle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
9/32"	Connecting Tubes with Yankauer Handle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1.5#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
2#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
2.5#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
4#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5#	Laryngeal Mask	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Fr8-Fr10 270mm	Urethral Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Fr12-Fr30 400mm	Urethral Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
12Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
14Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

16Fr	Closed Suction Catheter	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Heat & Moisture Exchanger Filters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
child	Heat & Moisture Exchanger Filters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT032-200	Breathing System Filters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6Fr	Mucus Extractor	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8Fr	Mucus Extractor	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10Fr	Mucus Extractor	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
12Fr	Mucus Extractor	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
14Fr	Mucus Extractor	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
12Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
14Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
15Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
16Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
18Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20Fr	Suction Catheters	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
10ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
60ml	Disposable Syringe Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT034-100	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT034-101	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT032-102	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT034-103	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

GT034-104	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT034-105	Disposable Infusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
100ml, 150ml	Infusion Set with Burette	IIa	100ml, 150ml	G2 073283 0046 Rev. 01, NB 0123
GT035-100	Disposable Blood Transfusion Sets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT039-200	Heparin Caps	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT033-100	Three way Stopcock and Extension Tube	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
GT039-100	Three way Stopcock and Extension Tube	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
0.3ml	Insulin Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
0.5ml	Insulin Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1ml	Insulin Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
15G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
16G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
17G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
18G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
19G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
21G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
22G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
23G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
24G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
25G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
26G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
27G	Hypodermic Needle	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
27g	Dental Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
30g	Dental Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.05 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.1 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.2 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.3 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

ZH-A: 0.4 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.5 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.6 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 0.8 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 1 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 1.2 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 2 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 2.5 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 3 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 4 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 5 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 6 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 10 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 12 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-A: 20 ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 2ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 2.5ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 3ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 4ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 5ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 6ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 10ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 12ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
ZH-B: 20ml	Auto-disable Syringe	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
29G	Insulin Pen Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
30G	Insulin Pen Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
31G	Insulin Pen Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
32G	Insulin Pen Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
33G	Insulin Pen Needles	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

S	Combi Stopper	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
M	Combi Stopper	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
L	Combi Stopper	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#10	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#11	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#12	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#12B	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#13	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#14	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#15	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#15C	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#16	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#18	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#19	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#20	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#21	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#22	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#23	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#24	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#25	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
#36	Disposable Surgical Blades	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Stainless Steel	Sterile Blood Lancets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Twist type	Sterile Blood Lancets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Capped type	Sterile Blood Lancets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
Soft clix type	Sterile Blood Lancets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
safety type	Sterile Blood Lancets	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
200ml	Wound Drainage Reservoir	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
400ml	Wound Drainage Reservoir	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
600ml	Wound Drainage Reservoir	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

800ml	Wound Drainage Reservoir	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1000ml	Wound Drainage Reservoir	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
13×15cm-4/6/8/16p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
15×15cm-4/6/8/16p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
15×20cm-4/6/8/16p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20×20cm-4/6/8/16p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20×30cm-4/6/8/16p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
30×30cm-2/3/4/6/8/16/24p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
30×40cm-2/3/4/6/8/16/24p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
40×40cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
40×45cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
45×45cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
40×50cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
50×50cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
50×60cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20×70cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20×80cm-2/3/4/6/8/16/24/32p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
20×100cm-2/3/4/6/8/16/24p	Lap Sponges	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
2.7g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
3.5g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
42g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
56.7g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
82g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
113g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

142g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
57g	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
1.0oz	Lubricating Jelly	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
5.5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
6.5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
7	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
7.5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
8.5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
9	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
9.5	Surgical Gloves	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
250ml	Humidifier Jar	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123
500ml	Humidifier Jar	IIa	N/A	G2 073283 0046 Rev. 01, NB 0123

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action

EC Certificate

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.:	HD 1709948-1
Manufacturer:	Nouvag AG St. Gallerstr. 23-25 9403 Goldach Switzerland
Products:	Medical devices Products included: - Suction pumps - Infiltration pumps - Motor systems for surgical and dental hand pieces - Surgical and dental hand pieces - Tube Sets, sterile - Blades, sterile - Rotating instruments - Attachments

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	3337456-30
Effective date:	2020-12-22
Expiry date:	2024-05-26
Issue date:	2020-12-22

TÜV Rheinland LGA Products

Roland Gruber
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Nouvag AG
Manufacturer address and contact details	Sankt Gallerstrasse 25 CH-9403 Goldach Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000018882

Authorised Representative name (if applicable) (EC Rep)	Nouvag GmbH
Authorised Representative address and contact details	Nouvag GmbH Schulthaißstr. 15 78462 Konstanz
Single Registration Number (SRN) (if available)	DE-AR-000005643

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH □ See attached schedule
Notified body number (if applicable)	0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 1709948-1 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-05-26 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☐ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	Nouvag AG
Location & Date	Goldach, 13.02.2024
Signature, Print Name, Title	Jasmin Schaible, Director Quality and Regulatory Affairs
Contact Details (at least email)	j.schaible@nouvag.com

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Directive Certificate number(s) to which this confirmation is made (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
HD 1709948-1	**2024-05-26**	**TÜV Rheinland LGA Products GmbH 0197**	**TÜV Rheinland LGA Products GmbH 0197**	**2028-05-26**	**n.a.**

Nutricia Medical Devices BV

DECLARATION OF CONFORMITY (medical devices)

DoC NMD 93928CE02_003 Flocare PEG set

Nutricia Medical Devices B.V., having its registered office at *Taurusavenue 167 / 2132 LS Hoofddorp (The Netherlands)*, hereinafter referred to as: "Nutricia", hereby declares that the distributed CE marked products, specified in the annexed product list, conform to the type(s) covered by the EC Certificate, reference number: 93928CE02, issued for the first time on 23 March 2016 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and fulfils the relevant provisions of the "Besluit Medische Hulpmiddelen", the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices, including all subsequent amendments.

Nutricia has implemented a quality assurance system for design, manufacture and final inspection in accordance to the provisions of Annex II of Council Directive 93/42/EC of June 14, 1993 and is subject to periodical surveillance.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, meet the provisions of the "Besluit Medische Hulpmiddelen", which is the Dutch transposition of the Council Directive 93/42/EEC" of June 14, 1993, concerning medical devices, which apply to them.

This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485:*2016*, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344.

This Declaration of Conformity covers the Flocare® products as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following production site:

- Nutricia Pharmaceutical (Wuxi) Co. Ltd. No. 17 XinMing Road, Wuxi, High-tech Development Zone, Jiangsu Province, P.R. China 214111

Hoofddorp, 11 July 2019

RA Manager

gitally signed by ME
mbaerts
te: 2019.07.11
:34:16 +02'00'

Mr. M.E. Lombaerts

Annexes

- Annex A Product list
- Annex B History sheet
- Annex C Discontinued product list

Nutricia Medical Devices BV

Annex A to the Declaration of Conformity (Product list)

Flocare® Percutaneous Endoscopic Gastrostomy sets, class IIb
(GMDN-code 35419 – Gastrostomy tube)

This product list belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_003 Flocare PEG set* and specifies the CE-marked products concerned that Nutricia Medical Devices B.V. intends to distribute in conformity with the provisions of the "Besluit Medische Hulpmiddelen", which is the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993, concerning medical devices. The following list identifies the products by name and article-number.

Product Code (REF)	Product name	Product Type	First Product LOT	Production Site
35427	Flocare® PEG-set	Ch10	201210K19	NP Wuxi
35428	Flocare® PEG-set	Ch14	201109K39	NP Wuxi
35429	Flocare® PEG-set	Ch18	201105K39	NP Wuxi
569866	Flocare® PEG-set – ENLock (for enteral feeding)	Ch18	201211L19	NP Wuxi
569869	Flocare® PEG-set – ENLock (for enteral feeding)	Ch10	201210K19	NP Wuxi
569870	Flocare® PEG-set – ENLock (for enteral feeding)	Ch14	201210K29	NP Wuxi
594820	Flocare® PEG set	ENFit Ch10	201602M89	NP Wuxi
594821	Flocare® PEG set	ENFit Ch14	201601M59	NP Wuxi
594822	Flocare® PEG set	ENFit Ch18	201601L59	NP Wuxi

Nutricia Medical Devices BV

Annex B to the Declaration of Conformity (History sheet)

Flocare® Percutaneous Endoscopic Gastrostomy sets, class IIb
(GMDN-code 35419 – Gastrostomy tube)

This history sheet belongs to the Declaration of Conformity identified by*: DoC NMD 93928CE02_003 Flocare PEG set* and specifies the revision history of the Declaration of Conformity, including revisions of the respective Quality System and CE certificates.

EN ISO 13485:2003, Quality System Certificate with reference number 59802, issued for the first time on 1 July 1996, revised on 15 December 2011 (multi-site structure), re-issued as EN ISO 13485:2012 on 1 September 2013, re-issued on September 30, 2016. *Revised on 2 July 2019 for ISO13485:2016 transition with the new Hoofddorp address.*

CE Marking of Conformity Certificate, reference number: 66211CE01**,** issued for the first time on April 1, 1997, re-issued on December 1, 2004, revised on February 26, 2007, re-issued on November 15, 2007, re-issued on September 1, 2010, re-issued on 1 September 2013, revised as certificate number 93928CE01 on 23 March 2016 (certificate 66211TE02 became obsolete), re-issued on September 12, 2017. *Revised on 2 July 2019 for the new Hoofddorp address.*

Rev. 003 *Update to new office address from Schiphol to Hoofddorp*
Update to ISO13485:2016 and revised CE certificates (new address)
Rev. 002 Update new CE certificate re-issued 12 September 2017. Update new ISO 13485 certificate effective 30 September 2016 exp 1 March 2019.
Rev. 001 Transfer to Annex II certification (ICC2016-009). Replacing DoC “Decl conf NMD 66211TE02_014 Flocare PEG set”
Inclusion first batch information

Nutricia Medical Devices BV

Annex C to the Declaration of Conformity (Discontinued Product list)

Flocare® Percutaneous Endoscopic Gastrostomy sets, class IIb
(GMDN-code 35419 – Gastrostomy tube)

This Annex belongs to the Declaration of Conformity identified by: *DoC NMD 93928CE02_003 Flocare PEG set* and specifies the discontinued products within the identified certificate. Product ranges are identified by first and last produced Batch/ LOT numbers. Products will be removed from the discontinued product list after 1 year of expiry of last produced batch.

Product Code (REF)	Product name	Product Type	First Product LOT	Last Product LOT	Production Site
35448	Flocare® PEG-set (with MLL XTREE connector)	Ch14	201111K39	201208L19	NP Wuxi
35449	Flocare® PEG-set (with MLL XTREE connector)	Ch18	201108N59	201206K39	NP Wuxi
35483	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH14	n/a never produced		NP Wuxi
35484	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH18	201211N99	201306K49	NP Wuxi

Nutricia Medical Devices B.V., kurios registruota buveinė yra Taurusavenue 167 / 2132 LS

Hoofddorp (Nyderlandai), toliau – Nutricia, pareiškia, kad platinami CE ženklu pažymėti gaminiai, nurodyti pridedamame produktų sąraše, atitinka tipą (-us) kuriam taikomas EB sertifikatas, nuorodos numeris: 93928CE02, pirmą kartą išduotas 23 d. 2016 m. kovo mėn. ir pristatė DEKRA Certification B.V., Arnhemas, Nyderlandai, notifikuotoji įstaiga Identifikavimo numeris 0344 ir atitinka atitinkamas „Besluit Medische Hulpmiddelen“, Nyderlandai perkėlė 1993 m. birželio 14 d. Tarybos direktyvą 93/42/EEB, dėl medicinos prietaisų, įskaitant visus vėlesnius pakeitimus. Nutricia įdiegė kokybės užtikrinimo sistemą projektavimui, gamybai ir galutiniam darbui patikrinimas pagal birželio 14 d. Tarybos direktyvos 93/42/EB II priedo nuostatas, 1993 m. ir yra periodiškai stebimas. Be to, užtikriname ir deklaruojame, kad platinami CE ženklu pažymėti gaminiai, kaip minėta ir priskiriami IIb klasei, atitinka „Besluit Medische Hulpmiddelen“, kuris yra Nyderlandai perkėlė 1993 m. birželio 14 d. Tarybos direktyvą 93/42/EEB dėl medicinos. prietaisus, kurie jiems taikomi. Šią deklaraciją patvirtina kokybės sistemos sertifikatas, pagrįstas darniaisiais standartais EN ISO 13485:2016, kokybės sistemos sertifikatas su nuorodos numeriu 59802, išduotas pirmą kartą 1996 m. liepos 1 d. ir pristatyta DEKRA Certification B.V., Arnhemas, Nyderlandai, Notifikuotos įstaigos dentifikavimo numeris 0344. Ši atitikties deklaracija apima Flocare® gaminius, nurodytus produktų sąraše priklauso šiai deklaracijai ir galioja visiems susijusiems gaminiams, pažymėtiems CE ženklu ir pagaminta šioje gamybos vietoje:

• Nutricia Pharmaceutical (Wuxi) Co. Ltd. Nr. 17 XinMing Road, Wuxi, aukštųjų technologijų plėtra Zona, Jiangsu provincija, P.R. Kinija 214111

Hoofddorp, 11 Liepa 2019

Vardas, pavardė//

Parašas//

Pareigos//

priedai

- A priedas Produktų sąrašas

- B priedas Istorijos lapas

- C priedas Nebegaminamas produktų sąrašas

Nutricia Medical Devices BV

Atitikties deklaracijos A priedas (gaminių sąrašas) Flocare® perkutaninės endoskopinės gastrostomijos rinkiniai, IIb klasė (GMDN kodas 35419 – Gastrostomijos vamzdelis). Šis gaminių sąrašas priklauso atitikties deklaracijai, kurią identifikavo: DoC NMD 93928CE02_003 Flocare PEG rinkinys ir nurodomi atitinkami CE ženklu pažymėti produktai, kuriuos Nutricia Medical Devices B.V. ketina platinti pagal „Besluit“ Medische Hulpmiddelen“, kuri yra Nyderlandų perkelta Tarybos direktyva 93/42/EEB 1993 m. birželio 14 d. dėl edicinos prietaisų. Toliau pateiktame sąraše produktai nurodomi pagal pavadinimą ir straipsnio numeris.

Produkto kodas	Produkto pavadinimas	Produkto tipas	Pirmo produkto LOT	Gamybos vieta
35427	Flocare® PEG-set	Ch10	201210K19	NP Wuxi
35428	Flocare® PEG-set	Ch14	201109K39	NP Wuxi
35429	Flocare® PEG-set	Ch18	201105K39	NP Wuxi
569866	Flocare® PEG-set – ENLock (for enteral feeding)	Ch18	201211L19	NP Wuxi
569869	Flocare® PEG-set – ENLock (for enteral feeding)	Ch10	201210K19	NP Wuxi
569870	Flocare® PEG-set – ENLock (for enteral feeding)	Ch14	201210K29	NP Wuxi
594820	Flocare® PEG set	ENFit Ch10	201602M89	NP Wuxi
594821	Flocare® PEG set	ENFit Ch14	201601M59	NP Wuxi
594822	Flocare® PEG set	ENFit Ch18	201601L59	NP Wuxi

Atitikties deklaracijos B priedas (Istorijos lapas) Flocare® perkutaninės endoskopinės gastrostomijos rinkiniai, IIb klasė (GMDN kodas 35419 – Gastrostomijos vamzdelis) Šis istorijos lapas priklauso atitikties deklaracijai, kurią identifikavo: DoC NMD 93928CE02_003 Flocare PEG nustato ir nurodo deklaracijos peržiūrų istoriją. Atitiktis, įskaitant atitinkamos kokybės sistemos ir CE sertifikatų peržiūras. EN ISO 13485:2003, kokybės sistemos sertifikatas su nuorodos numeriu 59802, išduotas pirmą kartą. 1996 m. liepos 1 d., peržiūrėta 2011 m. gruodžio 15 d. (daugelio objektų struktūra), pakartotinai išduotas kaip EN ISO 13485:2012 2013 m. rugsėjo 1 d., pakartotinai išduotas 2016 m. rugsėjo 30 d. Patikslintas 2019 m. liepos 2 d. ISO13485:2016 perėjimas su nauju Hoofddorp adresu. CE ženklinimo atitikties sertifikatas, nuorodos numeris: 66211CE01, išduotas pirmą kartą. 1997 m. balandžio 1 d., pakartotinai išduotas 2004 m. gruodžio 1 d., peržiūrėtas 2007 m. vasario 26 d., pakartotinai išduotas 2004 m. 2007-11-15, pakartotinai išduotas 2010-09-01, pakartotinai išduotas 2013-09-01, patikslintas kaip 2016 m. kovo 23 d. sertifikato numeris 93928CE01 (pažymėjimas 66211TE02 nebegalioja), Pakartotinai išduotas 2017 m. rugsėjo 12 d. Patikslintas 2019 m. liepos 2 d. dėl naujo Hoofddorp adreso. Rev. 003 Naujas biuro adresas iš Schiphol į Hoofddorp Atnaujinimas į ISO13485:2016 ir peržiūrėti CE sertifikatai (naujas adresas) 002 redakcija Atnaujinti naują CE sertifikatą, pakartotinai išduotą 2017 m. rugsėjo 12 d. Atnaujinti naują ISO 13485 sertifikatą, galiojantį 30 2016 m. rugsėjo mėn. galioja 2019 m. kovo 1 d. Rev. 001 Perkėlimas į II priedo sertifikavimą (ICC2016-009). DoC pakeitimas „Decl conf NMD 66211TE02_014 Flocare PEG rinkinys“ Įtraukti pirmosios partijos informaciją

Nutricia Medical Devices BV

Atitikties deklaracijos C priedas (nutrūkstamų gaminių sąrašas) Flocare® perkutaninės endoskopinės gastrostomijos rinkiniai, IIb klasė (GMDN kodas 35419 – Gastrostomijos vamzdelis) Šis priedas priklauso atitikties deklaracijai, nurodytai: DoC NMD 93928CE02_003 Flocare PEG rinkinys ir nurodytame sertifikate nurodomi nebegaminami produktai. Produktas diapazonai identifikuojami pagal pirmosios ir paskutinės pagamintos partijos / LOT numerius. Produktai bus pašalinti iš nutrauktų produktų sąrašo praėjus 1 metams nuo paskutinės pagamintos partijos galiojimo pabaigos.

Produkto kodas	Produkto pavadinimas	Produkto tipas	Pirmo produkto LOT	Paskutinio produkto LOT	Gamybos vieta
35448	Flocare® PEG-set (with MLL XTREE connector)	Ch14	201111K39	201208L19	NP Wuxi
35449	Flocare® PEG-set (with MLL XTREE connector)	Ch18	201108N59	201206K39	NP Wuxi
35483	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH14	n/a never produced		NP Wuxi
35484	Flocare® PEG-set (with MLL XTREE connector; NPSA)	CH18	201211N99	201306K49	NP Wuxi

Number: 2262711CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Nutricia Medical Devices B.V.

Taurusavenue 167
2132 LS Hoofddorp
The Netherlands
SRN ID.: NL-MF-000012729

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 93928CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Principal Certification Manager

First Issued: 27 July 2022 Date: 27 July 2022 Expiry date**: 27 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2262711CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

NBOG MDN 1202:

Non-active non-implantable devices for administration, channeling and removal of substances, including devices for dialysis (class Is)

Sterilization method: Ethylene oxide

Flocare Gravity Giving Sets:

- Flocare Gravity Pack Set
- Flocare Gravity Pack & Bottle Set
- Flocare Gravity TF Res. Set 2.0 L
- Flocare Gravity Set TF Res. Set 1.3 L
- Flocare Gravity Bottle Set

Flocare Accessories:

- Flocare Bolus Set
- Flocare Button Extension Set Plus
- Flocare Extension Set – 100 cm
- Flocare Button Extension Set
- Flocare TF Res. Pack Conn. 2.0 L – Cross
- Flocare TF Res. Pack Conn. 1.3 L – Cross
- Flocare Conn Two Pack – Cross Spike
- Flocare ENFIT Swivel Adapter

NBOG MDN 1202:

Non-active non-implantable devices for administration, channeling and removal of substances, including devices for dialysis (class IIa)

Flocare Infinity Giving Sets:

- Flocare Infinity Pack Set w/o DC Y-Port
- Flocare Infinity Pack Set w/o DC & w/o MP
- Flocare Infinity Pack Set w/o DC
- Flocare Infinity Pack Set
- Flocare Infinity Pack TwinLine Set

First Issued: 27 July 2022 Date: 27 July 2022 Expiry date**: 27 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2262711CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

- Flocare Infinity Pack Mobile Set
- Flocare Infinity Pack Mobile Set w/o MP
- Flocare Infinity Pack Mobile Set Y-Port
- Flocare Infinity Pack & Botte Mobile Set
- Flocare Infinity Pack & Bottle Set
- Flocare Infinity Bottle Set
- Flocare Infinity Bottle Set w/o MP
- Flocare Infinity Bottle Set Y-Port
- Flocare Infinity TF Res. Set 1.3
- Flocare Infinity TF Res. Set 2.0

First Issued: 27 July 2022 Date: 27 July 2022 Expiry date**: 27 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 2262711CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Conditions for or limitations to the validity of this certificate:

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

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	27 July 2022	93928CN44	First issue 2262711CE01
1			
2			

First Issued: 27 July 2022 Date: 27 July 2022 Expiry date**: 27 July 2027**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Sertifikatas

Numeris: **2262711CE01**

CE ATITIKTIES ŽENKLAS
MEDICINOS PRIETAISAMS

Atitikties vertinimo reglamentas 2017/745 dėl medicinos prietaisų, IX priedo I ir III skyriai

Gamintojas:

Nutricia Medical Devices B.V.
Taurusavenue 167
2132 LS Hoofddorp
Nyderlandai
SRN ID.: NL-MF-000012729

Produktų kategorijai:
Ilgalaikio naudojimo kateteriai enteriniam maitinimui

DEKRA suteikia teisę naudoti EB notifikuotosios įstaigos identifikavimo numerį, pavaizduotą toliau, kartu su CE Atitikties ženklinimas ant atitinkamų gaminių, atitinkančių reikalaujamą techninę dokumentaciją ir susirinkimas jiems taikomos ES reglamento nuostatos:

0344

Sertifikato priedas: 93928CN

DEKRA pareiškia, kad aukščiau minėtas gamintojas atitinka atitinkamus ES reglamento reikalavimus 2017/745, įskaitant visus vėlesnius pirmiau minėto atitikties vertinimo pakeitimus. gamintojas/ įgaliotasis atstovas yra periodiškai prižiūrimas, kaip reikalaujama atliekant atitinkamą atitikties įvertinimą pagal Reglamentą 2017/745.

DEKRA Sertifikacija B.V.

Parašas//

B.T.M. Holtus
Vykdantysis direktorius

Parašas//

J.A. van Vugt
Pagrindinis sertifikavimo vadovas

Pirmas leidimas: 2022 m. liepos 27 d
Data: 2022 m. liepos 27 d
Galiojimo laikas: 2027 m. liepos 27 d

Numeris: **2262711CE01**

CE ATITIKTIES ŽENKLAS
MEDICINOS PRIETAISAMS

Atitikties vertinimo reglamentas 2017/745 dėl medicinos prietaisų, IX priedo I ir III skyriai

Šis sertifikatas apima šiuos įrenginius / įrenginių grupes:

NBOG MDN 1202:

Neaktyvūs neimplantuojami prietaisai, skirti medžiagoms įvesti, nukreipti ir pašalinti, įskaitant dializės prietaisus (I klasė)

Sterilizacijos būdas: Etileno oksidas

Flocare Gravity Giving rinkiniai:

- Flocare Gravity Pack rinkinys
- Flocare Gravity Pack & Bottle Set
- Flocare Gravity TF Res. Rinkinys 2,0 l
- Flocare Gravity Set TF Res. Rinkinys 1,3l
- Flocare Gravity Bottle rinkinys

Flocare priedai:

- Flocare boliuso rinkinys
- „Flocare Button Extension Set Plus“.
- Flocare prailginimo rinkinys – 100 cm
- Flocare mygtuko plėtinių rinkinys
- Flocare TF Res. Pakuotės jungtis 2,0 L – kryžminė
- Flocare TF Res. Pakuotė Conn. 1,3 L – Kryžminis
- Flocare Conn Two Pack – Cross Spike
- Flocare ENFIT pasukamas adapteris

NBOG MDN 1202:

Neaktyvūs neimplantuojami prietaisai, skirti medžiagoms įvesti, nukreipti ir pašalinti, įskaitant dializės prietaisus (IIa klasė)

Flocare Infinity dovanų rinkiniai:

- Flocare Infinity Pack Set be DC Y prievado
- Flocare Infinity Pack rinkinys be DC ir be MP
- Flocare Infinity Pack Set be nuolatinės srovės
- Flocare Infinity Pack rinkinys
- Flocare Infinity Pack TwinLine rinkinys

Pirmas leidimas: 2022 m. liepos 27 d
Data: 2022 m. liepos 27 d
Galiojimo laikas: 2027 m. liepos 27 d

Numeris: **2262711CE01**

CE ATITIKTIES ŽENKLAS
MEDICINOS PRIETAISAMS
Atitikties vertinimo reglamentas 2017/745 dėl medicinos prietaisų, IX priedo I ir III skyriai

- Flocare Infinity Pack mobilusis rinkinys be MP
- Flocare Infinity Pack mobilusis rinkinys Y-Port
- Flocare Infinity Pack & Botte Mobile Set
- Flocare Infinity Pack & Bottle Set
- Flocare Infinity buteliukų rinkinys
- Flocare Infinity Bottle Set be MP
- Flocare Infinity butelių rinkinys Y-Port
- Flocare Infinity TF Res. 1.3 rinkinys
- Flocare Infinity TF Res. Nustatyti 2.0

Pirmas leidimas: 2022 m. liepos 27 d
Data: 2022 m. liepos 27 d
Galiojimo laikas: 2027 m. liepos 27 d

Numeris: **2262711CE01**

CE ATITIKTIES ŽENKLAS
MEDICINOS PRIETAISAMS

Atitikties vertinimo reglamentas 2017/745 dėl medicinos prietaisų, IX priedo I ir III skyriai

Šio sertifikato galiojimo sąlygos arba apribojimai:

- I klasės prietaisams notifikuotosios įstaigos atitikties vertinimas apsiriboja aspektais, susijusiais su sterilių sąlygų sukūrimas, užtikrinimas ir palaikymas

Sertifikato istorija

Bendrųjų specifikacijų ir suderintų standartų, kurių laikomasi, identifikavimas yra dokumentuojamas techniniame dokumente. Dokumentacija ir atlikti audito vertinimai. Juos galima atsekti naudojant DEKRA Certification B.V. sertifikavimo pranešimą.Sertifikavimo pranešime taip pat nurodoma būtina informacija, susijusi su gamintojo kokybės valdymo sistema, įskaitant patalpas.

Revizija	Sertifikato išdavimo data	Sertifikavimo pranešimas Nuoroda	Veikla
0	27 Liepos 2022	93928CN44	Pirmas suteikimas 2262711CE01
1			
2			

Pirmas leidimas: 2022 m. liepos 27 d
Data: 2022 m. liepos 27 d
Galiojimo laikas: 2027 m. liepos 27 d

/logo/

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Miunchenas · Vokietija

POLY MEDICURE LIMITED
Sector-68, IMT
Plot No. 34
121004 FARIDABAD, HARYANA
INDIJA

Jūsų nuoroda / laiškas	Mūsų nuoroda / pavadinimas	Tel. pratęsimas / el. paštas	Fakso pratęsimas	Data	Puslapis
	TPS3025_G10	keyor.baruwala@tuvsud.com		2024-03-12	1 iš 6

TÜV SÜD Product Service GmbH
Patvirtinimo laiškas
CL 105485 0010 00 red.

Nuoroda: TPS3025_G10

Suinteresuotiems asmenims,

Oficialaus prašymo, rašytinio susitarimo ir tinkamos priežiūros statuso patvirtinimas pagal Reglamentą (ES) 2023/607, kuriuo keičiamas reglamentas (ES) 2017/745 (toliau – MDR), kiek tai susiję su pereinamojo laikotarpio nuostatomis, taikomomis tam tikroms medicinos priemonėms ir in vitro diagnostikos medicinos priemonėms

Šiuo laišku TÜV SÜD Product Service GmbH, priskirta pagal MDR ir pažymėta NANDO numeriu 0123, patvirtiname, kad gavome oficialią paraišką pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašėme rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrą pastraipą su pirmiau nurodytu gamintoju, turinčiu šį SRN numerį

SRN numeris: IN-MF-000003380

Prietaisai, kuriems taikoma pirmiau minėta oficiali paraiška ir rašytinis susitarimas, nurodyti toliau pateiktose lentelėse.

- 1 lentelėje nurodyti prietaisai, dėl kurių buvo gauta MDR paraiška, sudarytas rašytinis susitarimas ir dėl kurių TÜV SÜD Product Service GmbH taip pat yra atsakinga už tinkamą prietaisų priežiūrą pagal taikomą direktyvą

- 2 lentelėje nurodyti prietaisai, dėl kurių buvo gauta MDR paraiška ir sudarytas rašytinis susitarimas, tačiau bendrovė TÜV SÜD Product Service GmbH dar neprisiėmė atsakomybės už tinkamą prietaisų priežiūrą pagal taikomą direktyvą.

Jei prietaisams, kuriems pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD) išduoti sertifikatai baigė galioti po 2021 m. gegužės 26 d. ir anksčiau nei 2023 m. kovo 20 d., tačiau jie nebuvo panaikinti, šiuo laišku taip pat patvirtinama, kadkuriems pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD) išduoti sertifikatai baigė galioti po 2021 m. gegužės 26 d. ir anksčiau nei 2023 m. kovo 20 d., tačiau jie nebuvo panaikinti, šiuo laišku taip pat patvirtinama, kad

- gamintojas pasirašė rašytinį susitarimą pagal MDR iki MDD/AIMDD sertifikato galiojimo pabaigos datos; arba
- pateikė pateikė įrodymų, kad valstybės narės kompetentinga institucija leido taikyti nuo taikytinos atitikties vertinimo procedūros nukrypti leidžiančią nuostatą arba išimtį atitinkamai pagal MDR 59 straipsnio 1 dalį arba MDR 97 straipsnio 1 dalį.

MDR 120 straipsnio 3 dalyje nustatyti pereinamojo laikotarpio terminai, taikomi šiame rašte nurodytiems prietaisams, su sąlyga, kad gamintojas ir toliau laikosi kitų MDR 120 straipsnio 3c dalyje nurodytų sąlygų, nurodyti žemiau:

- 2026 m. gegužės 26 d. – III klasės pagal užsakymą pagamintoms implantuojamosioms priemonėms
- 2027 m. gruodžio 31 d. – III klasės priemonių ir IIb klasės implantuojamųjų priemonių (išskyrus siūlus, kabes, dantų plombas, dantų breketus, dantų karūnėles, varžtus, pleištus, plokšteles, laidus, kaiščius, spaustukus ir jungtis) atveju.
- 2028 m. gruodžio 31 d. – kitiems IIb klasės prietaisams, IIa klasės, I klasės prietaisams, tiekiamiems rinkai sterilios būklės ir atliekantiems matavimo funkciją
- 2028 m. gruodžio 31 d. priemonėms, kurioms pagal MDD nereikia notifikuotosios įstaigos dalyvavimo, bet pagal MDR (pvz., I klasės priemonėms, kurios laikomos daugkartinio naudojimo chirurginiais instrumentais)

Mes pasiliekame teisę išrašyti sąskaitą faktūrą už bet kokį patvirtinimo laiško išdavimą, kopijas, pakeitimus ir (arba) pakeitimus, atsižvelgdami į pastangas

Patvirtinimo laiško galiojimą rasite www.tuvsud.com/ps-cert?q=cert:CL 105485 0010 Rev. 00

Kilus klausimams, prašome kreiptis į medical_devices@tuvsud.com.

Notifikuotosios įstaigos vardu TÜV SÜD Product Service GmbH,
2024-03-13

TÜV SÜD Product Service GmbH
Medical and Health Services

/Parašas/

Keyur Baruwala
Projektų vadovas (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

/Parašas/

Claus Matthias Mumme
Paraiškų tikrintojas (-a)

/Logo/

1 lentelė: Prietaisai, kuriems taikomas šis raštas ir už kuriuos TÜV SÜD Product Service GmbH taip pat yra atsakinga už tinkamą prietaisų priežiūrą pagal taikomą direktyvą:

Priemonės pavadinimas arba bazinis UDI-DI (pagal MDR apliciją)	MDR priemonių klasifikacija (kaip siūlo gamintojas ir patikrina paraiškos peržiūros metu)	Jei MDR piremonė yra pakaitinė priemonė, atitinkamas MDD/AIMDD priemonės identifikavimas	MDD/AIMDD sertifikato nuoroda (-os) apie priemones, kurioms taikoma MDR paraiška, ir NB identifikacija
1 priemonė **IV kaniulė / kateteris su/be saugos funkcija** **Bazinis UDI-DI: 890209510001CY**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
2 priemonė **Infuzijos rinkiniai** **Bazinis UDI-DI: 890209514001DU**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
3 priemonė **Srauto reguliatoriai** **Bazinis UDI-DI: 890209513100DQ**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
4 priemonė **Stabdymo kraneliai su/be prailginimo linija** **Bazinis UDI-DI: 890209513001DM**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
5 priemonė **Užpildytas švirkštas su 0,9% druskos tirpalu** **Bazinis UDI-DI: 890209590315GJ**	☒ IIb klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
6 priemonė **Arterinė kaniulė su/be saugos funkcija** **Bazinis UDI-DI: 890209513426ER**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
7 priemonė **Skirstytuvai su/be prailginimo linija** **Bazinis UDI-DI: 890209513710ER**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
8 priemonė **Mini vidurinės linijos kateteris (Periferinis kateteris)** **Bazinis UDI-DI: 890209513535EX**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
9 priemonė **Kraujo paėmimo adata ir laikiklis** **Bazinis UDI-DI: 890209588110H8**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
10 priemonė **Endotrachėjinis vamzdelis - paprastas/ su rankogaliu/sutvirtintas**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123

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Priemonės pavadinimas arba bazinis UDI-DI (pagal MDR apliciją)	MDR priemonių klasifikacija (kaip siūlo gamintojas ir patikrina paraiškos peržiūros metu)	Jei MDR piremonė yra pakaitinė priemonė, atitinkamas MDD/AIMDD priemonės identifikavimas	MDD/AIMDD sertifikato nuoroda (-os) apie priemones, kurioms taikoma MDR paraiška, ir NB identifikacija
Pagrindinis UDI-DI: 890209520150DV			
11 priemonė **AV fistulės adata su/be saugos funkcija** **Bazinis UDI-DI: 890209590030FX**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
12 priemonė **Dializatorius (Dializės filtras)** **Bazinis UDI-DI: 890209590365GZ**	☒ IIb klasė	☒ N/A	☒ Sertifikavimas tokiu būdu:: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
13 priemonė **Dezinfekuojanti angos apsauga** **Bazinis UDI-DI: 890209590309GP**	☒ IIa klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1 105485 0007 Rev. 00; NB# 0123
14 priemonė **Buteliuko prieigos smaigalys** **Pagrindinis UDI-DI: 890209513068EM**	☒ Is Klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1S 105485 0008 00 red.; NB# 0123
15 priemonė **Perkėlimo smaigalys** **Bazinis UDI-DI: 890209590314GG**	☒ Is Klasė	☒ N/A	☒ Sertifikavimas tokiu būdu: Sertifikatas # G1S 105485 0008 00 red.; NB# 0123

/Logo/

2 lentelė: Prietaisai, kuriems taikomas šis raštas ir už kuriuos TÜV SÜD Product Service GmbH NĖRA iš naujo atsakinga už tinkamą prietaisų priežiūrą pagal taikomą direktyvą:

Priemonės pavadinimas arba bazinis UDI-DI (pagal MDR apliciją)	MDR priemonių klasifikacija (kaip siūlo gamintojas ir patikrina paraiškos peržiūros metu)	Jei MDR piremonė yra pakaitinė priemonė, atitinkamas MDD/AIMDD priemonės identifikavimas	MDD/AIMDD sertifikato nuoroda (-os) apie priemones, kurioms taikoma MDR paraiška, ir NB identifikacija
-	-	-	-

/Logo/

Patvirtinimo laiško versijos istorija aiško versijų istorija

Data	**TÜV SÜD Product Service GmbH vidaus nuoroda, atsekama pagal kiekvieną laiško versiją**	**Veiksmas**
2024-03-13	TPS3025_G10	Pradinis leidimas

Kiwa Cermet Italia

TIBBİ CİHAZLAR BÖLÜMÜ
Granarolo deli'Emilia (BO), 2024/01/11
CL1/V3

Sayın

Plasti-med Plastik Medikal Ürünler San. Ve Tic. Ltd. Şti.
Deri OSB Mahallesi Yan San Cad. No: 13,34956 Tuzla/İstanbul TÜRKİYE

Onaylanmış Kuruluş Teyit Mektubu Referansı: CERBO0430223

Sayın İlgili,

Belirli tıbbi cihazlara ve in vitro tıbbi teşhis cihazlarına yönelik geçiş hükümlerine dair (EU)2017/745 ve (EU)2017/746 sayılı Yönetmelikleri değiştiren EU 2023/607 sayılı Yönetmelik çerçevesinde bir resmi başvurunun, yazılı anlaşmanın ve uygun gözetimin durumunun teyit edilmesi

Bu yazı, (EU)2017/745 (MDR) sayılı Yönetmeliğe göre belirlenmiş ve NANDO'da 0476 numarasıyla tanımlanmış bir Onaylanmış Kuruluş (NB) olan Kiwa Cermet Italia'nın, MDR Ek VII Bölüm 4.3 birinci alt paragraf uyarınca resmi bir başvuru almış ve MDR Ek VII Bölüm 4.3 ikinci alt paragraf uyarınca aşağıda belirtilen imalatçı ile bir yazılı anlaşma imzalamış olduğunu teyit eder:

Plasti-med Plastik Medikal Ürünler San. Ve Tic. Ltd. Şti.
Deri OSB Mahallesi
Yan San Cad.No:13,34956
Tuzla/İstanbul TÜRKİYE
SRN Numarası: TR-MF-000032251

Yukarıda belirtilen resmi başvuru ve yazılı anlaşma tarafından kapsanan cihazlar aşağıdaki Tablolarda belirtilmiştir.
Tablo 1, onlara ilişkin olarak bir MDR başvurusunun alınmış, bir yazılı anlaşmanın imzalanmış olduğu ve OK'nin onlara ilişkin olarak ilgili Direktif uyarınca mütekabil cihazların uygun gözetiminden de sorumlu olduğu cihazları belirtmektedir.

Tablo 2, onlara ilişkin olarak bir MDR başvurusunun alınmış, bir yazılı anlaşmanın imzalanmış olduğu ancak OK'nin ilgili Direktif uyarınca mütekabil cihazların uygun gözetimi sorumluluğunu henüz üstlenmemiş olduğu cihazları belirtmektedir.

93/42/EEC (MDD) sayılı Direktif uyarınca verilmiş olan ve iptal edilmiş olmaksızın 26 Mayıs 2021 tarihinden sonra ve 20 Mart 2023 tarihinden önce sona ermiş olan sertifikalarca kapsanan cihazların söz konusu olması halinde, bu yazı imalatçının MDR kapsamındaki yazılı anlaşmayı MDD sertifikasının sona erme tarihine kadar imzalamış olduğunu; veya bir Üye Devletin bir yetkili makamının ilgili cihazlara ilişkin olarak 20 Mart 2023 tarihine kadar sırasıyla MDR Madde 59(1) veya MDR Madde 97(1) uyarınca ilgili uygunluk değerlendirme prosedüründen bir istisna veya muafiyet vermiş olduğuna dair kanıt sunmuş olduğunu da teyit eder.

Tercüme edilmek üzere t
dilindeki (A5.m.) olan
tam ve doğru olarak çevi
YEMİNLİ TERCÜMAN:Mey

nekçe Sk. Moda İşhanı
21/110 Kızılay / ANKARA

Kiwa Cermet Italia

İmalatçının MDR Madde 120.3c'de ((AB) 2023/607 tarafından değiştirilen şekliyle) belirtilen diğer koşullara uymaya devam etmesine bağlı olarak, bu yazı tarafından kapsanan cihazlar için geçerli olan geçiş süreleri aşağıda gösterilmektedir:

- Sınıf III özel yapım implante edilebilir cihazlar için 26 Mayıs 2026
- Yerleşik teknolojiler (YT - sütürler, kelepçeler, diş dolguları, diş telleri, diş kaplamaları, vidalar, kamalar, protezler, teller, pimler, klipsler ve konektörler) hariç olmak üzere Sınıf III cihazlar ve Sınıf IIb implante edilebilir cihazlar için 31 Aralık 2027
- Steril durumda piyasaya arz edilen veya bir ölçüm fonksiyonuna sahip olan diğer Sınıf IIb cihazlar, Sınıf IIa, Sınıf I cihazlar için 31 Aralık 2028
- MDD uyarınca bir onaylanmış kuruluşun müdahil olmasını gerektirmeyen ancak onu MDR uyarınca gerektiren cihazlar için 31 Aralık 2028 (örneğin, yeniden kullanılabilir cerrahi aletler olarak nitelendirilen sınıf I cihazlar)

Onaylanmış Kuruluş adına
Dr.ssa Frabetti Alessia
Tıbbi Cihaz Bölümü Müdürü
(İmza)

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyeli şirket
Merkez: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO)
Tel. +39.051.4593.111 - Fax +39.051.763.382 - info@kiwacermet.it - www.kiwa.it
KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye: € 1.000.000,00 i.v.

Kiwa Cermet Italia

Tablo 1 : Bu yazı tarafından kapsanan ve OK'nin onlara ilişkin olarak ilgili Direktif uyarınca mütekabil cihazların uygun gözetiminden de sorumlu olduğu cihazlar

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı

Tablo 2: Bu yazı tarafından kapsanan ve onlara ilişkin olarak OK'nin ilgili Direktif uyarınca mütekabil cihazların uygun gözetiminden sorumlu OLMADIĞI cihazlar

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
YUMUŞAK DREN DRENAJ TORBALI / YARA DRENAJ SETLERİ (MİNİ TİP) / FLAT DRENLER / FLAT DRENLİ REZERVUARLI YARA DRENAJ SETLERİ WOUND/ ROUND DRENLER/ YARA DRENAJ REZERVUARLARI	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NAZAL OKSİJEN KANÜLÜ/ OKSİJEN MASKESİ / YÜKSEK KONSANTRASYONLU OKSİJEN MASKESİ/ OKSİJEN MASKESİ HORTUMU/ NEBULİZER KİT / NEBULİZER SET/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
YANKAUER ASPİRASYON UCU/ YANKAUER ASPİRASYON SETI/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
YANKAUER ASPIRASYON BAĞLANTI HORTUMU/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
BIYOPSI PUNCH/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
GUEDEL AIRWAY/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SOLUNUM EGZERSIZ CİHAZI ÜÇ TOPLU /	IIA	Aynı	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyeli şirket
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KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye: € 1.000.000,00 i.v.

Tercüme edilmek üzere
dilindeki ( ) olan
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YEMİNLİ TERCÜMAN:

enekşe Sk. Moda İşhanı
: 21/110 Kızılay / ANKARA

Kiwa Cermet Italia

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
HEPA FİLTRE / BAKTERİ VİRAL FİLTRE / BAKTERİ VİRAL HME FİLTRE/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
TEKRAR KULLANILABİLİR SUNİ SOLUNUM CİHAZI / TEKRAR KULLANILABİLİR MANUEL SUNİ SOLUNUM CİHAZ SETLERİ / TEK KULLANIMLIK SUNİ SOLUNUM CİHAZI/ TEK KULLANIMLIK MANUEL SUNİ SOLUNUM CİHAZ SETLERİ / SİLİKON MASKELER / ŞİŞİRİLEBİLİR MASKLER/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL BALON DİLATÖR / TRANSÜRETEROSKOPİK BALON DİLATÖR / TRANSÜRETEROSKOPİK BALON DİLATÖR ve ŞİŞİRME CİHAZI/ URETERAL BALON DİLATÖR ve ŞİŞİRME CİHAZI/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
KARMAN ŞIRINGA TEK VALF, STERİL / KARMAN ŞIRINGA TEK VALF / KARMAN ŞIRINGA ÇİFT VALF, STERİL / KARMAN ŞIRINGA ÇİFT VALF/ KARMAN ŞIRINGA ÇİFT VALF SET / KARMAN ŞIRINGA ÇİFT VALF STERİL / KARMAN ŞIRINGA TEK VALF SET / KARMAN KANÜL/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

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KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye: € 1.000.000,00 i.v.

Tercüme edilmek üzere b
dilindeki [illegible] olan
tam ve doğru olarak çevi
YEMİNLİ TERCÜMAN:Mevzi

ESRA
Yeminli Tercüman Bürosu
ad. Menekşe Sk. Moda İşhanı
Kat No: 21/110 Kızılay / ANKARA

Kiwa Cermet Italia

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
ASPİRASYON TORBASI, NON STERİL/ ASPİRASYON TORBASI / ASPİRASYON KANİSTERİ/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ASPİRASYON TORBASI HORTUMU/ KAPKON KONNEKTÖR/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
UZATMA HATTI/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NEPHROFLEX® BALON DİLATÖR / NEPHROFLEX® BALON DİLATÖR VE ŞİŞİRME CİHAZI /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ANESTEZİ DEVRESİ KORUGE/ ANESTEZİ DEVRESİ SMOOTHBORE/ ANESTEZİ DEVRESİ AYARLANABİLİR/ SOLUNUM DEVRESİ KORUGE/ SOLUNUM DEVRESİ SMOOTHBORE / SOLUNUM DEVRESİ AYLARLANABİLİR/ SOLUNUM DEVRESİ IPPB/ SOLUNUM DEVRESİ KOAKSİYEL/ SOLUNUM DEVRESİ TRANSPORT/ SOLUNUM DEVRESİ IPPB YARI KAPALI SİSTEM / KATETER MOUNT KORUGE ÇİFT YÖNLÜ DÖNER BAŞLIKLI / KATETER MOUNT SMOOTHBORE ÇİFT YÖNLÜ DÖNER BAŞLIKLI /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyeli şirket
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KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye: € 1.000.000,00 i.v.

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YEMİNLİ TERCÜMAN BÜROSU
[illegible]d. Menekşe Sk. Moda İşhanı
[illegible]t No: 21/110 Kızılay / ANKARA
[illegible]97 : 419 99 97 Fax: 425 47 88

Kiwa Cermet Italia

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
KATETER MOUNT AYARLANABİLİR ÇİFT YÖNLÜ DÖNER BAŞLIKLI / KATETER MOUNT KORUGE/ KATETER MOUNT SMOOTHBORE/ KATETER MOUNT AYARLANABİLİR / SOLUNUM TRAKEOSTOMİ DEVRESİ / TRAKEOSTOMİ DEVRESİ T KONEKTÖR / ANESTEZİ DEVRESİ, KORUGE, STERİL / ANESTEZİ DEVRESİ, SMOOTHBORE, STERİL / ANESTEZİ DEVRESİ, AYARLANABİLİR STERİL/ SOLUNUM DEVRESİ, KORUGE, STERİL / SOLUNUM DEVRESİ, SMOOTHBORE, STERİL / SOLUNUM DEVRESİ, AYARLANABİLİR STERİL/ SOLUNUM DEVRESİ IPPB, STERİL / SOLUNUM DEVRESİ KOAKSİYEL, STERİL / SOLUNUM DEVRESİ TRANSPORT STERİL / SOLUNUM DEVRESİ, IPPB YARI KAPALI SİSTEM, STERİL / KATETER MOUNT KORUGE ÇİFT YÖNLÜ DÖNER BAŞLIKLI STERİL / KATETER MOUNT SMOOTHBONE ÇİFT YÖNLÜ DÖNER BAŞLIKLI STERİL / KATETER MOUNT AYARLANABİLİR ÇİFT YÖNLÜ DÖNER BAŞLIKLI STERİL / KATETER MOUNT KORUGE, STERİL/ KATETER MOUNT SMOOTHBORE STERIL/ KATETER MOUNT AYARLANABİLİR STERİL / SOLUNUM TRAKEOSTOMİ DEVRESİ, STERİL / TRAKEOSTOMİ DEVRESİ T KONNEKTÖR, STERİL/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyeli sirket
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KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye:

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Menekşe Sk. Moda İşhanı
No: 21/110 Kızılay / ANKARA

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
Y –TUR IRRIGASYON SET / Y-TUR IRRIGASYON SET PUARLI /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
KAMERA KILIFI/	IS	Aynı	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
ENDOMETRİAL ÖRNEK ALMA KANÜLÜ/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
DAMLA AYAR SETİ/	IIA	Aynı	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL STENTLER / URETERAL STENT SETLERİ/ UZUN SÜRELİ URETERAL STENTLER / UZUN SÜRELİ URETERAL STENT / HİDROFİLİK URETERAL STENTLER / HİDROFİLİK URETERAL STENT SETLERİ / UZAYABİLEN URETERAL STENT SETLER / UZAYABİLEN URETERAL STENT SETLERİ / ENDOPYELOTOMİ ÜRETERAL STENT SETLERİ /	IIB	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

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YEMİNLİ TERCÜMAN:Mevzi

e Sk. Moda İşhanı
10 Kızılay / ANKARA
39 87 Faks: 425 47 83

Kiwa Cermet Italia

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
GİRİŞ İĞNELERİ / CHIBA İĞNELERİ	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
TAŞ TUTUCU / PYRAMID TAŞ ÇIKARMA SEPETİ / TAŞ ÇIKARMA SEPETİ ALTI TEL SIFIR UÇ NİTİNOL / TAŞ ÇIKARMA SEPETİ SIFIR UÇ NİTİNOL / HELİKAL TAŞ ÇIKARMA SEPETİ / YASSI TELLİ TAŞ ÇIKARMA SEPETİ / TAŞ ÇIKARMA FORSEPSİ / NİTİNOL PERKÜTAN SEPETİ / AMPLATZ RENAL DİLATÖR VE KILIF SETLERİ / AMPLATZ RENAL KILIFLAR / FASCİAL DİLATÖRLER / FASCİAL DİLATÖR SETLERİ / URETERAL KATETERLER / HİDROFİLİK URETERAL KATETERLER / HİDROFİLİK URETERAL GİRİŞ KATETERİ / İKİ KANALLI URETERAL KATETER / HİDROFİLİK URETERAL GİRİŞ KILIFI VE DİLATÖR SETLERİ / URETERAL DİLATÖR SETLERİ / SUPRAPUBİK KATETER SET POLİÜRETAN / SUPRAPUBİK KATETER SETLERİ SİLİKON-BALONLU / OCEAN TOUCH NİTİNOL HİDROFİLİK UÇLU KILAVUZ TEL / OCEAN NİTİNOL KILAVUZ TELİ /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

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KDV Tescil No: 00627711203 Vergi KN 035028203[illegible]

Tercüme edilmek üzere bana verilen [illegible] dilindeki (AGL) olan belgenin tam ve doğru olarak çevirisi [illegible]
YEMİNLİ TERCÜMAN: Meyzi [illegible]

ESRA yeminli tercüman bürosu
Menekşe Sk. Moda İşhanı
No: 21/110 Kızılay / ANKARA
[illegible]

Kiwa Cermet Italia

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
HİDROFİLİK NİTİNOL KILAVUZ TEL / HİDROFİLİK NİTİNOL SLIPPY KILAVUZ TEL / PTFE NİTİNOL HİDROFİLİK UÇLU KILAVUZ TEL / PTFE KILAVUZ TEL/ PTFE SÜPER SERT KILAVUZ TEL	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NEFROSTOMİ MALEKOT KATETERLER / NEFROSTOMİ MALEKOT KATETER SETLERİ/ RE-ENTRY MALEKOT KATETERLERİ / NEFROSTOMİ PIGTAIL KATETERLERİ / NEFROSTOMİ PIGTAIL SETLERİ / HİDROFİLİK PIGTAIL KATETERLERİ / HİDROFİLİK PIGTAIL KATETER SETLERİ/	IIB	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
CPAP BPAP MASKESI AĞIZ-BURUN / CPAP BPAP MASKESİ BURUN/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ENTERAL BESLENME TORBASI TEKLİ / ENTERAL BESLENME TORBASI ÇİFTLİ/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Teyit Yazısı Revizyon Tarihçesi

Rev.	Tarih	Aksiyon
00	11.01.2024	İlk Sertifikasyon

Yazının içeriği hakkında daha fazla bilgi veya yazının geçerliliğinin doğrulanması için lütfen medical@kiwa.com adresi ile ya da +39.051.4593.111 telefon numarası ile irtibata geçiniz.

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyeli şirket
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KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermaye: € 1.000.000,00 i.v.

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YEMİNLİ TERCÜMAN:Meyz

enekşe Sk. Moda İşhanı
: 21/110 Kızılay / ANKARA
417 99 07 Fax: 425 47 83

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/01/11
CL1/V3

Esteemed

Plasti-med Plastik Medikal Ürünler San. Ve Tic. Ltd. Şti.
Deri OSB Mahallesi Yan San Cad.No:13,34956 Tuzla/Istanbul TÜRKİYE

Notified Body Confirmation Letter Reference: CERBO0430223

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, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 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:

Plasti-med Plastik Medikal Ürünler San. Ve Tic. Ltd. Şti.
Deri OSB Mahallesi
Yan San Cad.No:13,34956
Tuzla/Istanbul TÜRKİYE
SRN Number: TR-MF-000032251

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 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 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.

i.v.

İşhanı
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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,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

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	MDD 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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Wound Drainage Sets Soft / Drains With Drainage Bag / Wound Drainage Sets (Mini Type) / Flat Drains / Wound Drainage Sets With Reservoirs And With Flat Drains / Round Drains / Wound Drainage Reservoirs	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Nasal Oxygen Cannula / Oxygen Mask / High Concentration Oxygen Mask / Oxygen Mask Tube / Nebulizer Kit / Nebulizer Set	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Yankauer Suction Handle / Yankauer Suction Set	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Yankauer Suction Connecting Tube	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Biopsy Punch	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Guedel Airway	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Respiratory Exercise Device w/ 3 Ball	IIA	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
HEPA FILTER / BACTERIAL VIRAL FILTER / BACTERIAL VIRAL W/ HME FILTER	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REUSABLE RESUSCITATOR DEVICE / REUSABLE MANUAL RESUSCITATOR DEVICE SET / DISPOSABLE RESUSCITATOR DEVICE / DISPOSABLE MANUAL RESUSCITATOR DEVICE SETS / SILICON MASKS / INFLATABLE MASK	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL BALLOON DILATOR / TRANSURETEROSCOPIC BALLOON DILATOR / TRANSURETEROSCOPIC BALLOON DILATOR w/ INFLATION DEVICE / URETERAL BALLOON DILATOR and INFLATION DEVICE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
KARMAN SYRINGE SINGLE VALVE, STERILE / KARMAN SYRINGE SINGLE VALVE / KARMAN SYRINGE DOUBLE VALVE,STERILE / KARMAN SYRINGE DOUBLE VALVE / KARMAN SYRINGE SINGLE VALVE SET, STERILE / KARMAN SYRINGE DOUBLE VALVE SET / KARMAN SYRINGE DOUBLE VALVE SET,STERILE / KARMAN SYRINGE SINGLE VALVE SET / KARMAN CANNULA	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SUCTION BAG, NON STERILE / SUCTION BAG / SUCTION CANISTER	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SUCTION BAG TUBE / KAPKON CONNECTOR	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
EXTENSION LINE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NEPHROFLEX® BALLOON DILATOR / NEPHROFLEX® BALLOON	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Sk. Moda Işhanı
Kızılay / ANKARA
Tel: Fax:

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DILATOR W/ INFLATION DEVİCE			
ANESTHESIA CIRCUIT CORRUGATED / ANESTHESIA CIRCUIT SMOOTHBORE / ANESTHESIA CIRCUIT EXTENDABLE / BREATHING CIRCUIT CORRUGATED / BREATHING CIRCUIT SMOOTHBORE / BREATHING CIRCUIT EXTENDABLE / BREATHING CIRCUIT IPPB / BREATHING CIRCUIT COAXIAL / BREATHING CIRCUIT TRANSPORT / BREATHING CIRCUIT IPPB SEMI CLOSED SYSTEM / CATHETER MOUNT CORRUGATED W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT SMOOTHBORE W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT EXTENDED W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT CORRUGATED / CATHETER MOUNT SMOOTHBORE / CATHETER MOUNT EXTENDED / BREATHING TRACHEOSTOMY CIRCUIT / TRACHEOSTOMY CIRCUIT T CONNECTOR / ANESTHESIA CIRCUIT CORRUGATED, STERILE / ANESTHESIA CIRCUIT SMOOTHBORE, STERILE / ANESTHESIA CIRCUIT EXTENDABLE, STERILE / BREATHING CIRCUIT CORRUGATED, STERILE / BREATHING CIRCUIT SMOOTHBORE, STERILE /	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Moda İşhanı
Kızılay / ANKARA

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BREATHING CIRCUIT EXTENDABLE, STERILE / BREATHING CIRCUIT IPPB, STERILE / BREATHING CIRCUIT COAXIAL, STERILE / BREATHING CIRCUIT TRANSPORT, STERILE / BREATHING CIRCUIT IPPB SEMI CLOSED SYSTEM, STERILE / CATHETER MOUNT CORRUGATED W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT SMOOTHBORE W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT EXTENDED W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT CORRUGATED, STERILE / CATHETER MOUNT SMOOTHBORE, STERILE / CATHETER MOUNT EXTENDED, STERİLE / BREATHING TRACHEOSTOMY CIRCUIT, STERILE / TRACHEOSTOMY CIRCUIT T CONNECTOR, STERILE			
Y IRRIGATION SET / Y-TUR IRRIGATION SET W/ MANUAL PRESSURE PUMP	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
CAMERA COVER	IS	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
ENDOMETRIAL CELL SAMPLER	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
I.V FLOW REGULATOR	IIA	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL STENTS / URETERAL STENT SETS / LONG TERM URETERAL STENTS / LONG TERM URETERAL STENT SETS / HYDROPHILIC URETERAL	IIB	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

İş Hanı
/ ANKARA
425 47 83

Kiwa Cermet Italia

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
STENTS / HYDROPHILIC URETERAL STENT SETS / MULTILENGHT URETERAL STENTS / MULTILENGHT URETERAL STENT SETS / ENDOPYELOTOMY URETERAL STENTS SETS			
INTRODUCER NEEDLE / CHIBA NEEDLE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
STONE HOLDER / PYRAMID STONE BASKET / STONE BASKET SIX WIRE TIPLESS NITINOL / STONE BASKET TIPLESS NITINOL / HELICAL STONE BASKET / FLAT WIRE STONE BASKET / STONE GRASPER FORCEPS / NITINOL PERCUTANEOUS BASKET / AMPLATZ RENAL DILATORS AND SHEATS SET / AMPLATZ RENAL SHEATHS / FASCIAL DILATORS / FASCIAL DILATOR SETS / URETERAL CATHETERS / HYDROPHILIC URETERAL CATHETERS / HYDROPHILIC URETERAL ACCESS CATHETER / DUAL LUMEN URETERAL CATHETER / HYDROPHILIC URETERAL ACCESS SHEATH AND DILATOR SETS / URETERAL DILATOR SETS / SUPRAPUBIC CATHETER SETS POLYURETHANE / SUPRAPUBIC CATHETERSETS SILICONE-W/ BALLOON / OCEAN TOUCH NITINOL HYROPHILIC TIP GUIDE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

k. Moda İşhanı
Kızılay / ANKARA

Kiwa Cermet Italia

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
WIRE / OCEAN NITINOL GUIDEWIRE / HYDROPHILIC NITINOL GUIDEWIRE / HYDROPHILIC NITIONOL SLIPPY GUIDEWIRE / PTFE NITINOL GUIDEWIRE WITH HYDROPHILIC TIP / PTFE GUIDEWIRE / PTFE SUPER STIFF GUIDEWIRE			
NEPHROSTOMY MALECOT CATHETERS / NEPHROSTOMY MALECOT CATHETER SETS / RE-ENTRY MALECOT CATHETERS / NEPHROSTOMY PIGTAIL CATHETERS / NEPHROSTOMY PIGTAIL SETS / HYDROPHILIC PIGTAIL CATHETERS / HYDROPHILIC PIGTAIL CATHETER SETS	IIB	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
CPAP BPAP Masks Ora-Nasal / CPAP BPAP Masks Nasal	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Enteral Feeding Bag Single / Enteral Feeding Bag Double	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Confirmation Letter Revision History

Rev. *Rev.*	Date *Date*	Action *Azione*
00	11.01.2024	Initial Certification

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111

Moda İşhanı
Kızılay / ANKARA
Fax: 425 47 83

T.R.
MINISTRY OF HEALTH
Türkiye Drug and Medical Device Agency

Number: E-61749811-511.99-1374208
Subject: About the Announcement Application Numbered 2023/KK-1

05.02.2024

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Deri OSB Mahallesi. Yan Sanayi Cad. No:13 Tuzla/İstanbul

Reference: Your letter dated 19.01.2024, numbered E-48535386-511.01.99-2884086, with transaction follow-up 5833083

Your application, which is about your request for extension of the document validity period of the EC certificate numbered 1984-MDD-11-100 and which is included in the referenced letter, has been examined.

"The European Parliament and Council Regulation Numbered (EU) 2023/607 amending the transitional provisions for certain medical devices and in vitro diagnostic medical devices of the Regulations Numbered (EU) 2017/745 and (EU) 2017/746" was published in the EU Official Journal on **20 March 2023** with a view to entering into force as of **20 March 2023**, with purpose of the European Commission to reduce the risk of being unable to supply medical devices.

Within the scope of the harmonization efforts with the EU's current medical device legislation; our Regulations titled *"the Regulation on Amending the Medical Device Regulation"* and *"the Regulation on Amending the In Vitro Diagnostic Medical Devices Regulation"* were published in the Official Gazette dated **2/4/2023**, in parallel with *the European Parliament and Council Regulation Numbered (EU) 2023/607*, and the said amendments were made in *the Medical Device Regulation* and in *the In Vitro Diagnostic Medical Device Regulation.*

In this context, our Announcement ***numbered 2023/KK-1*** and titled ***"Announcement on the Implementation of the Provisions of the Regulation Numbered (EU) 2023/607"***, in which the procedures and principles of the applications for the implementation of the said transitional provisions are explained, was published on our Agency's website and ÜTS Portal on **3/4/2023** and entered into force. With our Announcement titled ***"Announcement Numbered 2023/KK-5 Revising the Announcement Numbered 2023/KK-1 on the Implementation of the Provisions of the Regulation Numbered (EU) 2023/607"*** that we published on **14/8/2023,** some provisions of ***the Announcement Numbered 2023/KK-1*** were revised and additional provisions were added to the relevant Announcement.

Accordingly, the relevant application has been evaluated as per ***"the Announcement Numbered 2023/KK-1 on the Implementation of the Provisions of the Regulation Numbered (EU) 2023/607"*** and extension of the validity period until 31/12/2028 of the EC Certificate numbered 1984-MDD-11-100 in the application has been found appropriate. In this context, I request you be advised and take necessary action with respect to making document registration/update application on ÜTS by adding to the system this responding letter of ours and its annexes, as per our Announcement titled ***the Announcement Numbered 2023/KK-2 on the Implementation of the Provisions of the Regulation Numbered (EU) 2023/607.***

I kindly request your information and necessary

Dr. Mehmet Hakan FIRAT
Deputy President of Agency
f. President of Agency

Annex 1: Manufacturer's Declaration (14 Pages)
Annex 2: Confirmation Letter (17 Pages)
Annex 3: Surveillance Letter (4 Pages)
Annex 4: EC Certificate (10 Pages)

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T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI

Sayı : E-61749811-511.99-1374208 05.02.2024
Konu : 2023/KK-1 Sayılı Duyuru Başvurusu Hk.

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Deri OSB Mahallesi. Yan Sanayi Cad. No:13 Tuzla/İstanbul

İlgi : 19.01.2024 tarihli, E-48535386-511.01.99-2884086 sayılı, 5833083 işlem takipli yazınız

İlgi yazıda yer alan ve 1984-MDD-11-100 numaralı EC sertifikasının belge geçerlilik süresinin uzatılması talebinizle ilgili olan başvurunuz incelenmiştir.

Avrupa Komisyonu'nun tıbbi cihazların tedarik edilememe riskini azaltmak amacıyla "*(AB) 2017/745 sayılı ve (AB) 2017/746 sayılı Tüzükleri belirli tıbbi cihazların ve in vitro tanı amaçlı tıbbi cihazların geçiş hükümlerini tadil eden (AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü*" **20 Mart 2023** tarihinden itibaren yürürlüğe girecek şekilde **20 Mart 2023** tarihinde AB Resmi Gazetesinde yayımlanmıştır.

AB'nin güncel tıbbi cihaz mevzuatına uyum çalışmaları kapsamında;*(AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü'ne* paralel olarak, "*Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" ve "*İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" adlı Yönetmeliklerimiz **2/4/2023** tarihli Resmi Gazete 'de yayımlanmış olup, *Tıbbi Cihaz Yönetmeliği* ve *İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde* söz konusu değişikler yapılmıştır.

Bu kapsamda, söz konusu geçiş hükümlerinin uygulanmasına yönelik başvuruların usul ve esaslarının açıklandığı "***2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru***" adlı Duyurumuz **3/4/2023** tarihinde Kurumumuz web sitesinde ve ÜTS Portal'da yayımlanarak yürürlüğe girmiştir. **14/8/2023** tarihinde yayımladığımız "***2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuruyu Revize Eden 2023/KK-5 Sayılı Duyuru***" adlı Duyurumuz ile birlikte ***2023/KK-1 Sayılı Duyurunun*** bazı hükümleri revize edilmiş ve ilgili Duyuruya ilave hükümler eklenmiştir.

Bu minvalde ilgili başvuru "***2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru***" kapsamında değerlendirilmiş olup, başvurudaki 1984-MDD-11-100 *numaralı EC Sertifikasının* geçerlilik süresinin 31/12/2028 tarihine kadar uzatılması uygun görülmüştür. Bu bağlamda, **"2023/KK-2 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru"** adlı Duyurumuz kapsamında ÜTS'de bu cevabi yazımızı ve eklerini de sisteme ekleyerek belge kayıt/güncelleme başvurusu yapılması hususunda;

Bilgilerinizi ve gereğini rica ederim.

Dr. Mehmet Hakan FIRAT
Kurum Başkanı a.
Kurum Başkan Yardımcısı

Ek1: İmalatçı Beyanı (14 Sayfa)
Ek2: Teyit Mektubu (17 Sayfa)
Ek3: Gözetim Yazısı (4 Sayfa)
Ek4: EC Sertifikası (10 sayfa)

İzmir Ce
A Blok 2. K
Tel: 419 8

Bu belge, güvenli elektronik imza ile imzalanmıştır.
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