

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



NOT

Andri

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

5. In / at 8090 Zürich / Zurich

Bestätigt / Certified
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° 1179274/2020

9. Stempel/Siegel, Stamp/seal 10. Ur



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9. Stempel/Siegel, Stamp/seal	10. Un



S. Overkott

Handwritten signature or scribble in blue ink.

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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 Canto

8. unter Nr. / under N° 1179273/2020

9. Stempel/Siegel, Stamp/seal 10. Unte _____





EU DECLARATION OF CONFORMITY

Manufacturers Name : Marflow AG
Manufacturers Address : Alte Landstrasse 54, 8546, Islikon, Switzerland.
Telephone, fax and e-mail: +41 44 709 01 0, +41 44 710 21 36
marflow@marflow.ch

Single Registration Number

(SRN): CH-MF-000023766

Product Details : *It is given an Annex-I*

Classification : *Class Is and Class IIa*

Conformity assessment

route: This declaration of conformity has been prepared in accordance with Annex I, Annex II, Annex III, Annex IV and Annex VI.

We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration of conformity is issued under the sole responsibility of "Marflow AG".

Harmonized Standards

EN ISO 13485:2016

EN ISO 14971:2019

Place/ Date of Issue

Authorized Name, Surname and Signature

Annex-I

DESCRIPTION	GMDN	BASIC UDI	INTENDED PURPOSE
Amplatz & Mini Amplatz Dilator & Kit, Amplatz Sheath	46448	76300006025KE, 76300006026KG, 76300006027KJ	This device is used for nephrostomy tract sequential dilation and the placement of a sheath.
Braided Shaft Catheter	38821	76300006004K6	This device is used for external drainage from Genitourinary Tract, Percutaneous procedure.

Double J Stent / Kit (Short term)	34926	76300006030K7, 76300006032KB, 76300006034KF, 76300006036KK, 76300006038KP, 76300006040KA,	Double J Stent / Kit (Short term) is used for internal drainage from Kidney to Bladder.
Arthroscope Kit	62570	76300006092KV	Scopes are used to examine the inside of the body throughout a body passageway or opening to see inside an organ.
Bilbao Dotter Catheter	38561	76300006078L3	Bilbao Dotter Catheter Tube is used through channel of endoscope to provide short duration internal access for delivery of nutrition or medication to small bowel.
Biliary Drainage Catheter/ Biliary Plastic Stent	10696	76300006082KS	Biliary Drainage Catheter is the type of stents used to drain the bile ducts
Biliary Metal Stent	43691	76300006053KK	The biliary stent is intended for maintaining biliary luminal patency in malignancy.
Biopsy Forceps	46679	76300006049KU	Biopsy Forceps are intended for endoscopic histological sampling of various tissue sites within various parts of the body via the operating channel of endoscopic instruments.
Chiba Needle	35886	76300006001JY	Chiba Needle used for Percutaneous Nephrostomy procedures, Cytological biopsies, needle-aspirations, thoracentesis exploratory punctures, to inject contrast dyes.
Cholangioscope Kit	36640	76300006093KX	Scopes are used to examine the inside of the body throughout a body passageway or opening to see inside an organ.
Cysto Catheter/ Kit	46587	76300006073KR, 76300006074KT	The Cysto catheter offers a simplified system for bladder drainage by Suprapubic placement of a Foley catheter.
Cysto-nephroscope Kit	46722	76300006095L3	Scopes are used to examine the inside of the body throughout a body passageway or opening to see inside an organ.
Double Lumen Catheter	32158	76300006069L2	The Dual lumen catheter is used for drainage of urine, contrast injection, Ureteral Dilation & placement of safety guidewire.

EBUS Needle	38825	76300006051KF	EBUS allows physicians to perform a technique known as transbronchial needle aspiration (TBNA) to obtain tissue or fluid samples from the lungs and surrounding lymph nodes without conventional surgery.
Endopyelotomy Stent/ Kit	58005	76300006018KH, 76300006019KK	Endopyelotomy Stent / Kit is used for internal drainage from Kidney to Bladder For any irregular pylem stricture.
Esophageal Dilator	35009	76300006048KS	Esophageal Dilators are used over a pre-positioned Chase Spring Tip Guide wire or equivalent for dilation of esophageal strictures.
Esophageal Stent	43573	76300006052KH	The Esophageal Stents are intended for maintaining esophageal luminal patency in malignant strictures.
EUS Needle	38825	76300006050KD	The Endoscopies ultrasound needle (EUS)- FNA is used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The Endoscopies ultrasound needle (EUS)- FNB is used to sample targeted submucosal lesions, mediastinal masses, lymph nodes and intraperitoneal masses within or adjacent to the gastrointestinal tract through the accessory channel of an ultrasound endoscope.
Fascial Dilator/ Set	46448	76300006008KE, 76300006009KG	Fascial Dilator / Set is used for dilatation of percutaneous track over guidewire for fascial dilation.
Foley Catheter	34096	76300006126KM	A Foley Catheter is used to drain urine in situations where one cannot urinate on their own.
Gastro Stone Basket	46452	76300006055KP	The Gastro Stone Basket is used for endoscopic removal of gallstones from the biliary system of the human body. Stone removal procedure is carried through an endoscope.
G-paw Stone Basket	46452	76300006091KT	Stone Baskets are used to retrieve stones or to restraint stone migration from or within the urinary system..

Hemoclip	61207	76300006054KM	Hemoclip is intended for endoscopic clip placement within the gastrointestinal tract for the purpose of haemostasis for mucosal / submucosal defects, bleeding ulcers, arteries and polyps.
Guidewire	46691	76300006022K8, 76300006023KA, 76300006024KC, 76300006025KE	Guidewire is a device used to facilitate the placement of endourological instruments during diagnostic or treatment procedures.
IP Needle	61503	76300006002K2	IP Needle is used for Initial Puncture for all percutaneous applications.
Jejunal Feeding Catheter Tube	38564	76300006075KV	Jejunal feeding tube is used when patients require feeding past stomach directly into jejunum & it is used to enhance absorption of nutrients & minimize risks of gastric feeding including gastric reflux & aspiration.
Loop Basket	46452	76300006046KN	The Loop Basket is intended for use in endoscopic retrieval of foreign objects, food bolus, tissue fragments & excised tissue such as polyps from the gastrointestinal tract.
Malecot Catheter/ Kit	10735	76300006010JZ, 76300006011K3	Malecot Catheter /Kit is used for external drainage of viscous liquids from Renal Pelvis or Bladder for PCN & Suprapubic procedures respectively.
Mono J Stent/ Kit	58005	76300006006KA, 76300006007KC	Mono J Stent Kit is used for external drainage from kidney through urethra.
Multiband Ligator	34137	76300006044KJ	Multiband Ligator is used to endoscopically ligate esophageal varices at or above the gastro-esophageal junction.
Multistage OTW Balloon Dilator	45712	76300006080KN	The Balloon Dilator is intended to endoscopically dilate strictures of the alimentary tract. Also indicated in adults for endoscopic dilatation of the sphincter of Oddi following sphincterotomy.
Nasal Biliary Drainage Catheter (NBDC)	47059	76300006076KX	It is used for Biliary duct drainage through nasal passage & also for treatment of strictures in ductile system.

Nephrostomy Balloon Dilator	10735	76300006081KQ	Nephrostomy Balloon is used to dilate the musculofascial tract and renal capsule establishing a Nephrostomy tract during a percutaneous procedure.
PCN Catheter/ Kit	10735	76300006014K9, 76300006015KB	PCN Catheter / Kit (Abscess Drainage Catheter / Kit) device is used for the temporary drainage by direct puncture through the skin into the Kidney for the distal obstruction. Used for percutaneous placement in the renal pelvis for nephrostomy drainage.
PEG Kit	47656	76300006047KQ	The PEG kit is intended for Percutaneous Endoscopic Gastro stoma (PEG) procedure for placement of a enternal nutrition feeding tube to patients requiring nutritional support.
Perk Basket	46452	76300006003K4	This extractor is designed to provide rapid atraumatic stone extraction during percutaneous nephrolithotomy (PCNL). Perk baskets are used for kidney stone removal.
PTA Balloon Catheter	47732	76300006042KE, 76300006043KG	The PTA Balloon Catheter is single-use, disposable medical device intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.
PTBD Catheter	10696	76300006079L5	PTBD Catheter is used for Transhepatic Biliary Drainage of biliary duct through the use of an indwelling catheter.
Re-entry Malecot Catheter	34924	76300006012K5	Re-Entry Malecot Catheter / Kit is used for percutaneous placement in the renal pelvis for Nephrostomy Drainage (Internal and external drainage).
Sclectrotherapy Needle	64114	76300006077KZ	Sclectrotherapy needles are used for injection of sclectrotherapeutic solution in toesophageal varices.
Screw Dilator	46448	76300006068KY	Screw Dilator is used for one step dilatation. This can be used instead of sequential dilatation.

Stone Basket	46452	76300006020K4	Stone Baskets are used to retrieve stones or to restraint stone migration from or within the urinary system..
Stone Grasper	46685	76300006021K6	Stone Grasper are used to retrieve stones or to restraint stone migration from or within the urinary system..
Stone Stop	46452	76300006089L8	Stone Baskets are used to retrieve stones or to restraint stone migration from or within the urinary system..
Suprapubic Catheter/ Kit	34924	76300006016KD, 76300006017KF	Suprapubic Catheter / Kit is used to drain urine from the bladder when someone cannot urinate.
Ureteral Balloon Dilator	34926	76300006005K8	Ureteral Balloon Dilator is a dilator used for ureteral dilation prior to ureteral stone manipulation or ureteroscopy, as well as dilation of the intramural ureter & urinary tract. Also used for widening the ureteral stricture.
Ureteral Catheter	34926	76300006013K7	Ureteral Catheter used for external ureteral drainage and for retrograde pyelogram and navigation of the tortuous ureter through the urethra.
Ureteral Dilator/ Set	38821	76300006028KL, 76300006029KN	Ureteral Dilator / Set are the set of dilators used for dilatation of the ureter, prior to ureter renoscopy and also for sequential dilatation of the intramural tunnel and urethra and / or stone manipulation.
Ureteroscopy Kit	36640	76300006094KZ	Scopes are used to examine the inside of the body through a body passageway or opening to see inside an organ.
Urethral Dilator/ Set	64677	76300006070KK, 76300006071KM	These are used for dilation of the urethra prior to urethra renoscopy and also for sequential dilatation of the intramural tunnel and urethra and/ or stone manipulation.
URS Forceps	46685	76300006072KP	URS Forceps is a device used for grasping, manipulating and extracting calculi from ureteral and renal pelvis.
X-circle Basket	46452	76300006090KR	Stone Baskets are used to retrieve stones or to restraint stone migration from or within the urinary system..

Mechanical lithotripter	12379	76300006045KL	Mechanical Lithotripter are used to mechanically crush the stones in the biliary duct or pancreatic duct when other methods of endoscopic removal have failed.
IUI Catheter	45846	76300006097L7	This device is used to artificial intra-uterine insemination.
Penile Clamp	37882	76300006098L9	A penile clamp is worn externally to control incontinence in men. This clamp help patients manage urine leakage.
Evacuator	48179	76300006099LB	This device is used for evacuating irrigation solution containing surgical specimens, calculi or blood clots from the bladder and trans urethral resection of the prostate (TURP).
Polypectomy Snare	62615	76300006083KU	Polypectomy Snare is used for endoscopic excision of polyps monopolar electrosurgical unit & retrieval of foreign bodies G. I tract
TURP Loop/ Cutting Electrodes	61875	76300006096L5	TURP LOOP / Cutting Electrodes are used to remove prostate tissue in the form of small chips during TURP procedures.
Sphincterotome	58039	76300006084KW	Sphincterotome is used to access common bile duct when standard method of cannulation have been exhausted. It can be used for the treatment of diseases of the papilla of Vater, such as sphincter of Oddi dysfunction (SOD) or to facilitate subsequent therapeutic biliary interventions, such as stone extraction, stenting.

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_Ila	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_Ila

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

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



Reg. Numero / <i>Reg. Number</i>	MED 23028	Revisione / <i>Revision</i>	4
Primo rilascio / <i>First issue date</i>	2003-12-01	Valido da / <i>Valid from</i>	2018-12-01
Scadenza / <i>Valid until</i>	2023-12-01	Ultima modifica / <i>Last change date</i>	2018-12-01

Pagina / Page 1 di / of 4

Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

MEDIFLY S.r.l.

Sede Legale e Operativa / Registered and operational headquarter:

Via Statale, 12
41036 Medolla, MO - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi sterili e non, per aspirazione chirurgica / *Sterile and not sterile devices for surgery aspiration*
Dispositivi sterili per drenaggio toracico e drenaggio ferite / *Sterile devices for thoracic drainage and wound drainage*
Dispositivi sterili per raccolta urine/diuresi oraria / *Sterile devices for urine collection and hourly diuresis*
Dispositivi sterili per infusione, irrigazione e lavaggio / *Sterile devices for infusion, irrigation and washing*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* 30-31/07/2018

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* 04/10/2018



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero / <i>Reg. Number</i>	MED 23028	Revisione / <i>Revision</i>	4
Primo rilascio / <i>First issue date</i>	2003-12-01	Valido da / <i>Valid from</i>	2018-12-01
Scadenza / <i>Valid until</i>	2023-12-01	Ultima modifica / <i>Last change date</i>	2018-12-01

Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate*

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*

Dispositivi sterili e non, per aspirazione chirurgica / *Sterile and not sterile devices for surgery aspiration*

Classe di rischio / *Risk class:*

II a

Codice NANDO / *NANDO codes:*

MD 0102, MDS 7006.1

Marca / *Brandname:*

Medifly

Modello / *Model:*

Flyvac

Codici / *Codes:*

F01xxxx/F01xxxxxx(αβ)/F01xxxxxx(αβ)/F01xxxxxx(αβγδ)

Tipologia / *Medical Devices:*

Dispositivi sterili per drenaggio toracico e drenaggio ferite / *Sterile devices for thoracic drainage and wound drainage*

Classe di rischio / *Risk class:*

II a

Codice NANDO / *NANDO codes:*

MD 0102, MDS 7006.1

Marca / *Brandname:*

Medifly

Modello / *Model:*

Drenofly

Codici / *Codes:*

F06xxxx(γ)

Modello / *Model:*

Thorafly

Codici / *Codes:*

F03xxxx(γ)

CERTIFICATE



Reg. Numero / <i>Reg. Number</i>	MED 23028	Revisione / <i>Revision</i>	4
Primo rilascio / <i>First issue date</i>	2003-12-01	Valido da / <i>Valid from</i>	2018-12-01
Scadenza / <i>Valid until</i>	2023-12-01	Ultima modifica / <i>Last change date</i>	2018-12-01

Pagina / Page 3 di / of 4

Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate*

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*

Dispositivi sterili per raccolta urine/diuresi oraria / *Sterile devices for urine collection and hourly diuresis*

Classe di rischio / *Risk class:*

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / *restricted to the aspects concerned the maintenance of sterile conditions*

Codice NANDO / *NANDO codes:*

MD 0102, MDS 7006.1

Marca / *Brandname:*

Medifly

Modello / *Model:*

Meterfly

Codici / *Codes:*

F05xxxx

Modello / *Model:*

Urofly

Codici / *Codes:*

F02xxxx

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero / Reg. Number	MED 23028	Revisione / Revision	4
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Scadenza / Valid until	2023-12-01	Ultima modifica / Last change date	2018-12-01

Pagina / Page 4 di / of 4

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi sterili per infusione, irrigazione e lavaggio / Sterile devices for infusion, irrigation and washing

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0102, MDS 7006.1

Marca / Brandname:

Medifly

Modello / Model:

Flyline

Codici / Codes:

F04xxxx/F04aBxxxx(γ)/F04aBxxxx(γ)/F04aBxxxx(γ)/F04aBxxxx(γ)

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
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E-mail: info@kiwacermet.it
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Officer
edi



Organismo Notificato n. 0476
Notified Body nr. 0476





Registracijos numeris MED 23028

Peržiūra 4

Pirma išdavimo data 2003-12-01

Galioja nuo 2018-12-01

Galioja iki 2023-12-01

Paskutinė koregavimo data 2018-12-01

CE sertifikatas

Mes patvirtiname, kad remiantis atliktais auditais, organizacijos produkcijos kokybės užtikrinimo sistema:

MEDIFLY S.r.l.

Registruota adresu:

Via Statale, 12

41036 Medolla, MO - Italija

Direktyva 93/42/EEB V priedas pakeistas Italijoje Dlgs. 46, 1997 m. 02 24 d.

Šiems medicinos prietaisams

Sterilūs ir nesterilūs prietaisai chirurgijai

Sterilūs prietaisai krūtinės ir pooperaciniam drenavimui

Sterilūs prietaisai šlapimo surinkimui ir dažnam šlapinimuisi

Sterilūs prietaisai infuzijoms, irigacijoms ir plovimui

Žr. techninių duomenų priedą

Sertifikatas yra CERMET reguliacijos objektas ir galioja tik paminėtiems medicinos prietaisams.

Leidimo data: 2018.07.30-31

Paskutinės peržiūros data: 2018.10.04

Vadovas
Giampiero Belcredi

CE
Notifikuota įstaiga nr. 0476

MEDIFLY S.R.L.
VIA STATALE 12, NR. 141
41036 MEDOLLA MO IT – Italia

24/01/2024

Notified Body Confirmation Letter
Reference: 128330

To whom it may concern,

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

This letter confirms that, ICIM SPA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDIFLY S.R.L.
VIA STATALE 12, NR. 141
41036 MEDOLLA MO IT – Italia

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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

- 26 May 2026 for Class III custom-made implantable devices

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

On behalf of the Notified Body,

ICIM SPA
 Piazza Don Enrico Mapelli, 75
 2099 Sesto San Giovanni MI
 Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
FLYVAC	IIa	N.A.	MED23028 NB 0476
UROFLY	Is	N.A.	MED23028 NB 0476
THORAFLY	IIa	N.A.	MED23028 NB 0476
THORAFLY – THORASET	IIa	N.A.	MED23028 NB 0476
FLYLINE	Is	N.A.	MED23028 NB 0476
DRENOFLY	IIa	N.A.	MED23028 NB 0476

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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
12/01/2024	01	Initial issue
24/01/2024	02	Modification as a consequence of stipulation of agreement to transfer supervision.

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

>

MEDIFLY S.R.L.
VIA STATALE 12, NR. 141
41036 MEDOLLA MO IT –
Italija

24/01/2024

Notifikuotosios įstaigos patvirtinimo laiškas
Nuoroda: 128330

Suinteresuotiems asmenims

Oficialaus prašymo, rašytinio susitarimo ir tinkamos priežiūros statuso patvirtinimas pagal Reglamentą (ES) Nr. 2023/607, kuriuo iš dalies keičiamos reglamentų (ES) 2017/745 ir (ES) 2017/746 nuostatos dėl pereinamojo laikotarpio nuostatų, taikomų tam tikriems medicinos prietaisams ir in vitro diagnostikos medicinos prietaisams

Šiuo raštu patvirtinama, kad ICIM SPA, notifikuotoji įstaiga (NB), paskirta pagal Reglamentą (ES) 2017/745 (MDR) ir identifiukuota numeriu 0425 NANDO, gavo oficialų prašymą pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrą pastraipą su šiuo gamintoju:

MEDIFLY S.R.L.
VIA STATALE 12, NR. 141
41036 MEDOLLA MO IT –
Italija

Prietaisai, kuriems taikoma pirmiau minėta oficiali paraiška ir rašytinis susitarimas, yra nurodyti toliau pateiktose lentelėse. 1 lentelėje nurodyti prietaisai, dėl kurių buvo gauta paraiška dėl MDR, sudarytas rašytinis susitarimas ir dėl kurių NB taip pat yra atsakinga už tinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą. 2 lentelėje nurodyti prietaisai, dėl kurių buvo gauta paraiška dėl MDR ir sudarytas rašytinis susitarimas, tačiau NB dar neprisiėmė atsakomybės už tinkamą atitinkamų prietaisų priežiūrą pagal taikomą direktyvą.

Jei tai priemonės, kurioms taikomi sertifikatai, išduoti pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD), kurie nustojo galioti po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20 d., tačiau nebuvo atšaukti, šiuo raštu taip pat patvirtinama, kad gamintojas pasirašė rašytinį susitarimą pagal MDR iki MDD/AIMDD sertifikato galiojimo pabaigos datos; arba pateikiami įrodymai, kad valstybės narės kompetentinga institucija iki 2023 m. kovo 20 d. leido taikyti nuo taikytinos atitikties vertinimo procedūros leidžiančią nukrypti nuostatą arba išimti pagal atitinkamai MDR 59 straipsnio 1 dalį arba MDR 97 straipsnio 1 dalį atitinkamoms priemonėms.

Toliau pateikiami pereinamieji terminai, taikomi šiame laiške nurodytiems prietaisams, jei gamintojas nuolat laikosi kitų sąlygų, nurodytų MDR 120.3c straipsnyje (su pakeitimais, padarytais (ES) 2023/607):

- 2026 m. gegužės 26 d. III klasės pagal užsakymą pagamintiems implantuojamiems prietaisams

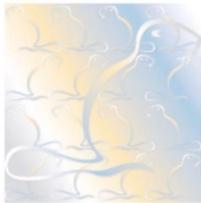
Patvirtinimo laiško peržiūros istorija

Data	Pastaba: vidinė nuoroda atsekama pagal kiekvieną versiją laiško	Veiksmai
2024-01-12	01	Pirminių sveikatos pažymėjimų išdavimas
24/01/2024	02	Pakeitimai dėl susitarimo perduoti priežiūrą.

Likę jūsų žinioje, kad galėtume paaiškinti šio laiško turinį, pasinaudojame šia galimybe ir perduodame geriausius linkėjimus.

Dotai. Edoardo Dossena
Produktų pardavimo vadybininko produktų
sertifikavimas, patikrinimai ir direktyvos
ICIM S.p.A.
/parašas/
/antspaudas/

Dotai. Dario Bruno
„Narbutas International“
ICIM S.p.A.
/parašas/
/antspaudas/



Reg. Numero / <i>Reg. Number</i>	MED 31417	Revisione / <i>Revision</i>	5
Primo rilascio / <i>First issue date</i>	2016-12-12	Valido da / <i>Valid from</i>	2016-12-12
Scadenza / <i>Valid until</i>	2021-12-11	Ultima modifica / <i>Last change date</i>	2019-06-10

Pagina / Page 1 di / of 2

Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

Meditalia S.r.l.

Sede Legale e Operativa / Registered and Operational Headquarter:

Via della Piana 1
23030 Lovero Valtellino, SO - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Sistema per trattamento di emocomponenti / *Blood component treatment system*

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero / Reg. Number	MED 31417	Revisione / Revision	5
Primo rilascio / First issue date	2016-12-12	Valido da / Valid from	2016-12-12
Scadenza / Valid until	2021-12-11	Ultima modifica / Last change date	2019-06-10

Pagina / Page 2 di / of 2

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Sistema per trattamento di emocomponenti / Blood component treatment system

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Solutran® hemo - Sistemi Sacche Accessori con e senza filtro per leucodeplezione (sacche singole, sacche quaduple, sacche sestuple, sistemi di pooling)/ Solutran® hemo Ancillary System Bags with or without leucodepletion filter (single bags, quadruple bags, sextuple bags, pooling System)

Modello / Model:

Solutran®hemo BioNest - BioNest System ; BioNest System for adult platelet donors; BioNest Transfer Bag

Codice NANDO / NANDO codes:

MD 0102, MDS 7006 Moist heat

Modello / Model:

Solutran®hemo Blood Bags – Sacca sangue singola, sacca sangue doppia, sacca sangue tripla con e senza filtro per leucodeplezione, sacca sangue quadrapla con e senza filtro per leucodeplezione / Solutran®hemo – Single Blood bag, Double Blood bag, Triple Blood bag with or without leucodepletion filter, Quadruple Blood bag with or without leucodepletion filter

Marca / Brandname:

TRANSMED

Modello / Model:

Transmed Blood Bag – Sacca sangue singola con Sodio citrato / Single blood bag Na - Citrate

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numeris	MED 31417	Patikrinimas	5
Pirmo išleidimo data	2016-12-12	Galioja nuo	2016-12-12
Galioja iki	2021-12-11	Paskutinio keitimo data	2019-06-10
		Puslapis	1 iš 2

EC Kokybės užtikrinimo sistemos Sertifikatas

Mes patvirtiname, kad remiantis atliktais auditais, pilna Kokybės užtikrinimo sistema organizacijai:

Meditalia S.r.l.

Registruota ir veikianti būstinė:
Via della Piana 1
23030 Lovero Valtellino, SO - Italija

Atitinka taikomas 93/42/EEC Direktyvos reikalavimus su pakeitimais, Priedas II be 4 punkto, perkelti Italijoje Dlgs. 46 of 1997/02/24 susijusiais su šiais medicinos prietaisais:

Kraujo komponentų gydymo sistema

analizė:: datuojama 05/01/2019

vadovas

i

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadrano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
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E-mail: info@kiwacermet.it
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CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numeris	MED 31417	Patikrinimas	5	
Pirmo išleidimo data	2016-12-12	Galioja nuo	2016-12-12	
Galioja iki	2021-12-11	Paskutinio keitimo data	2019-06-10	
			Puslapis	2 iš 2

Prie Sertifikato pridedamas techninis lapas

Medicinos prietaisų identifikacija:

Medicinos prietaisai:

Kraujo komponentų gydymo sistema

Rizikos klasė:

II b

NANDO kodai:

MD 0102, MDS 7006 Etileno oksido dujų sterilizavimas (EOG)

Modelis:

Solutran® hemo Pagalbinės sistema krepšiai su ar be leukodepletijos filtru (viengubi maišai, keturgubi maišai, šešiagubai maišai, telkimo sistema)

Modelis:

Solutran®hemo BioNest - BioNest Sistema ; BioNest Sistema suaugusiems trombocitų donorams; BioNest transferiniai maišai

NANDO kodai:

MD 0102, MDS 7006 Drėgna šilumas

Modelis:

Solutran®hemo – Viengubas kraujo maišas, Dvibubas kraujo maišas, Trigubas kraujo maišas su ar be leukodepletijos filtru, Keturgubas kraujo maišas su ar be leukodepletijos filtru

Prekės ženklas:

TRANSMED

Modelis:

Viengubas kraujo maišas Na - Citratasa

Šiam Sertifikatui taikomos Kiwa Cermet Italia taisyklės ir jis galioja tik viršuje minimiems Medicinos prietaisams, kurie yra tikrinami. Techninis lapas yra ineguota šio Sertifikato dalis.

racijų vadovas

Icredi

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadrano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



Ministero della Salute

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

DGDMF/3/P/I.5.l.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 dispositivi 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 <i>ENDOSCOPIC HEMOSTATIC CLIP WITH APPLICATOR, USABLE WITH DUODENOSCOPE, AND FOR POST POLYPECTOMY PERFORATION AND BLEEDING TREATMENT</i>	MED-XXX-CLP
CESTELLI PER ESTRAZIONE <i>STONE EXTRACTION BASKETS</i>	MED-XXX-BAS
FILI GUIDA PER GASTROENTEROLOGIA <i>GASTROENTEROLOGY GUIDE WIRES</i>	MED-XXX-WIR
PINZE PER BIOPSIA <i>BIOPSY FORCEPS</i>	MED-XXX-FOR
PINZE PER RECUPERO CORPI ESTRANEI <i>RETRIEVAL FORCEPS</i>	MED-XXX-RET
ANSE PER POLIPECTOMIA E/O RECUPERO <i>POLYPECTOMY AND/OR RETRIEVAL SNARES</i>	MED-XXX-SNA MED-XXX-NET MED-XXX-MUL MED-XXX-MUC
ANSA PER POLIPECTOMIA A FREDDO/DISPOSABLE POLIPECTOMY <i>COLD SNARE</i>	MED-XXX-COLD
CATETERI A PALLONCINO PER ESTRAZIONE CALCOLI <i>DISPOSABLE STONE EXTRACTION BALLOON</i>	MED-2XX-EXT MED4XX-EXT
AGHI PER INIEZIONE ENDOSCOPICA <i>ENDOSCOPIC INJECTION NEEDLES</i>	MED-XXX-INJ
VALVOLE BIOPTICHE <i>BIOPSY VALVES</i>	V-OLY/V-PENTAX
PINZA MULTIFUNZIONE PER BIOPSIA E RESEZIONE POLIPI DIMINUITIVI A FREDDO E MULTIPRELIEVO / <i>MULTIFUNCTIONAL FORCEPS FOR BIOPSIES AND COLD RESECTION OF DIMINUTIVE POLYPS AND MULTIBITE</i>	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**.*

Non è consentita la riproduzione o la pubblicazione del presente documento su carta, stampa, supporti elettronici o siti web.

It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

È consentito mostrarlo o consegnarlo solo su richiesta delle autorità doganali o sanitarie competenti del paese di importazione.

It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

RM

eej

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

We, as the manufacturer declare under our sole responsibility:

Page 1 of 4

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/EX

Location & Date Palermo 2024-08-05

Signature, Print Name, Title PEZZINO SEBASTIAN

Contact Details (at least email) mednatio@meditalias

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

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)

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 Polyectomy 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 balloon	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	



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

Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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

Puslapis 1 iš 2

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 Lipnių 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 Vyrų Kateteriai, Ginekologiniai Rinkiniai,
Ginekologiniai Šepetėliai, Nazalinės Spekulės, Irigaciniai Švirkštai,
Injekcinės Servetėlės, Kolostomijos Maišeliai,
Nazofaringiniai Vamzdeliai, Medinės Liežuvio Mentelės,
Vyrų/Moterų 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, Pediatriiniai Šlapimo Surinkėjai, Klizmavimo Maišelis, Sterilus Vaginalinis
Aplikatorius,
Medium Transportavimo Tepinėliai, Vienkartinis anestezinis laringoskopas**

Puslapis 2 iš 2

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

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.

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.

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,
Torshamngatan 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 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

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

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

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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

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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

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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	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
M	Oxygen Masks	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
L	Oxygen Masks	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
XL	Oxygen Masks	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Nasal Oxygen Cannula	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
child	Nasal Oxygen Cannula	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
infant	Nasal Oxygen Cannula	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
Neonate	Nasal Oxygen Cannula	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
2M	Oxygen Connection Tubings	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
GT117-300	CPR Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
GT117-400	CPR Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Manual Resuscitators	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
pediatric	Manual Resuscitators	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
infant	Manual Resuscitators	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
000#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
00#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
0#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
1#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
2#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
3#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
4#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
5#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
6#	Anesthesia Mask	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
Adult	Anesthetic Breathing Circuits	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
child	Anesthetic Breathing Circuits	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123

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

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

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

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

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

Intertek Medical Notified Body AB

Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden

Telephone +46 8 750 00 00, Fax +46 8 750 60 30,

Email: IMNB@intertek.com

www.intertek.se

Registered office: As address

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

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800ml	Wound Drainage Reservoir	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
1000ml	Wound Drainage Reservoir	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
13x15cm-4/6/8/16p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
15x15cm-4/6/8/16p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
15x20cm-4/6/8/16p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
20x20cm-4/6/8/16p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
20x30cm-4/6/8/16p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
30x30cm-2/3/4/6/8/16/24p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
30x40cm-2/3/4/6/8/16/24p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
40x40cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
40x45cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
45x45cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
40x50cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
50x50cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
50x60cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
20x70cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
20x80cm-2/3/4/6/8/16/24/32p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
20x100cm-2/3/4/6/8/16/24p	Lap Sponges	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
2.7g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
3g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
3.5g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
5g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
42g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
56.7g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
82g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123
113g	Lubricating Jelly	Ila	N/A	G2 073283 0046 Rev. 01, NB 0123

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Email: IMNB@intertek.com

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Registered office: As address

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

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.

D

B.
M

First Issued: 27 July 2022

Date: 27 July 2022

Expiry date: **27 July 2027**

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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**

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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**

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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**

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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 ženklavimu 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

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 müteakbil 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 müteakbil 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.



Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyelik 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.

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-üyelî şirket
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Tercüme edilmiş
dilindeki (AS)
tam ve doğru ola
YEMİNLİ TERCÜME



U. Moda İşhanı
Gizliay / ANKARA
T. No: 252 21 02

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

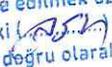
Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütakabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı

Tablo 2: Bu yazı tarafından kapsanan ve onlara ilişkin olarak OK'nin ilgili Direktif uyarınca mütakabil 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, mütakabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
YUMUŞAK DREN DREN AJ TORBALI / YARA DREN AJ SETLERİ (MİNİ TİP) / FLAT DRENLER / FLAT DREN Lİ REZERVUARLI YARA DREN AJ SETLERİ WOUND/ ROUND DRENLER/ YARA DREN AJ 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 SETİ/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
YANKAUER ASPİRASYON 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 EGZERSİZ CİHAZI ÜÇ TOPLU /	IIA	Aynı	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.



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Tercüme edilmek üzere
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tam ve doğru olarak
YEMİNLİ TERCÜMAN


YEMİNLİ TERCÜMAN BİRLİĞÜ
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21/110 Kızılay / ANKARA
0312 444 4444 E-Posta: iletisim@yemimli.com.tr

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, müteakbil 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 / TRANSÜRETEROSKOPIK BALON DİLATÖR / TRANSÜRETEROSKOPIK BALON DİLATÖR ve ŞİŞİRME CİHAZI/ URETERAL BALON DİLATÖR ve ŞİŞİRME CİHAZI/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
KARMAN ŞİRINGA TEK VALF, STERİL / KARMAN ŞİRINGA TEK VALF / KARMAN ŞİRINGA ÇİFT VALF, STERİL / KARMAN ŞİRINGA ÇİFT VALF/ KARMAN ŞİRINGA ÇİFT VALF SET / KARMAN ŞİRINGA ÇİFT VALF STERİL / KARMAN ŞİRINGA TEK VALF SET / KARMAN KANÜL/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.



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Menekşe Sk. Moda İşhanı
No: 21/110 Kızılay / ANKARA
T : 312 310 0370 Faks: 312 310 0370

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, müteakbil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
ASPIRASYON TORBASI, NON STERİL/ ASPIRASYON TORBASI / ASPIRASYON KANİSTERİ/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ASPIRASYON 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 AYARLANABİLİR/ SOLUNUM DEVRESİ IPPB/ SOLUNUM DEVRESİ KOAKSİYEL/ SOLUNUM DEVRESİ TRANSPORT/ SOLUNUM DEVRESİ IPPB YARI KAPALI SİSTEM / KATETER MOUNT KORUGE ÇİFT YÖNLÜ DÖNER BAŞLIKLİ / KATETER MOUNT SMOOTHBORE ÇİFT YÖNLÜ DÖNER BAŞLIKLİ /	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.

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İncekşe Sk. Moda İşhanı
21/110 Kızılay / ANKARA
*19 96 07 Faks: 425 47 83

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, müteakbil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
KATETER MOUNT AYARLANABİLİR ÇİFT YÖNLÜ DÖNER BAŞLIKLİ / 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 BAŞLIKLİ STERİL / KATETER MOUNT SMOOTHBONE ÇİFT YÖNLÜ DÖNER BAŞLIKLİ STERİL / KATETER MOUNT AYARLANABİLİR ÇİFT YÖNLÜ DÖNER BAŞLIKLİ STERİL / KATETER MOUNT KORUGE, STERİL/ KATETER MOUNT SMOOTHBORE STERİL/ KATETER MOUNT AYARLANABİLİR STERİL / SOLUNUM TRAKEOSTOMİ DEVRESİ, STERİL / TRAKEOSTOMİ DEVRESİ T KONNEKTÖR, STERİL/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.



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Sk. Moda İşhanı
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 06460 Fone: 0312 277 88 88

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, müteakbil 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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KDV Tescil No: 00627711203 Verg

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Moda İşhanı
Azırlay / ANKARA
Fax: 425 47 88

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, müteakbil 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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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, müteakıl 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 MASKESİ AĞIZ-BURUN / CPAP BPAP MASKESİ BURUN/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ENTERAL BESLENME TORBASİ TEKLİ / ENTERAL BESLENME TORBASİ 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-üyelik şirket
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dilindeki (SİL) tam ve doğru olarak
YEMİNLİ TERCÜMAT



k. Moda İşhan
Kızılay / ANKARA
7 Fax: 425 47 83

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.



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 Erhetti Alessia

 **Kiwa Cermet Italia S**
Headquarters: Via Cac
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VAT Registration No. I

and coordination of Kiwa Italia Holding Srl

 08.000,00 i.v.

 oda Işhan
ay / ANKARA
0531 428 47 88

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.

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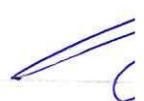


İ. Moda İşhanı
Kızılay / ANKARA
FAX: 444 44 44

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 DEVICE			
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.



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 VAT Registration No. 00627711203 – Tax



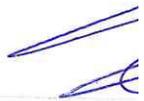
Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, 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, STERILE / 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.



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.



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 VAT Registration No. 00627711203 -





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 NITINOL SLIPPER 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



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

100
TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI



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)

This document has been signed by secure electronic signature.

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Moda İşhanı
Zılay / ANKARA
Fax: 425 47 83

Tercüme edilmek üzere banyo
dilineki (ASU) olan belgeyi
tam ve doğru olarak çevirdiğim
YEMİNLİ TERCÜMAN :



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



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

05.02.2024

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 "In 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 In Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde söz konusu değişiklikler 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)

AB
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Bu belge,

Belge Doğrulama Kodu: 0ZW56ZW56ZW56ak1UZmxXZw...

Belge Takip Adresi: <https://www.turkiye.gov.tr/saglik-titck-ebys>

Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA

Telefon No: (0 312) 218 30 00 Faks No: (0 312) 218 34 60

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Kep Adresi: titck@hs01.kep.tr



EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Deri OSB Mahallesi. Yan Sanayi Cad. No:13 Tuzla/İstanbul/Turkey

The products defined at the enclosure which is the part of this certificate and contains six pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3567.09
Date of first issue: 25 July 2011
Date of last issue: 25 May 2021
Revision Number: 11
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex II for Class Is devices covered by this certificate and found that the quality system meets the requirements of MDD Annex II.

25 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Stone Baskets	Nitinol Helical
	Nitinol Flat Wire
	Nitinol Triprong
	Nitinol Tipless
	Nitinol Percutaneous Basket
	3 Wires
	Spiral Stone Holder
Urodynamic Catheters And Sets	Urodynamic Cystometry Catheter and Set
	Hydrophilic Urodynamic Cystometry Catheter
	Urodynamic Cystometry Catheter & UPP Catheter
	Hydrophilic Urodynamic Cystometry Catheter & UPP Catheter
Renal Dilator And Sets	Amplatz Renal Sheat
	Amplatz Renal Dilatör and Sheat Set
	Fascial Dilator and Sets
	Percutaneous Tract Dilatation Kit with Nephrostomy Balloon Dilator
	Screw Dilator
	Percutaneous Tract Dilatation Kit with Amplatz Renal Dilator Set
Ureteral Catheters	Dual Lumen Ureteral Catheters
	Ureteral Catheters
	Hydrophilic Ureteral Catheters
Ureteral Access Sheat And Dilator Sets	Hydrophilic Ureteral Access Sheat& Dilator Set
	Ureteral Access Sheat& Dilator Set
	Nottingham Dilator Catheter
	Ureteral Dilators and Sets

25 May 2021, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 2/6

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
IUI Catheter	IUI Catheters
	IUI Catheter Cannula
Suprapubic Catheter And Sets	Suprapubic Catheters and Sets
	Silicone Suprapubic catheter and Sets
	Suprapubic Catheter Set-Standard
	Suprapubic Catheter Set With Balloon
Needles	TLA Introducer Needle
	Initial Puncture Needles
	Chiba Needle
Guide Wires	Guide Wire- Nitinol
	Hydrophilic Guide Wire- Nitinol
	Zebra Guide Wire- Nitinol
	Guide Wire-PTFE
	Guide Wire J Type
	Ocean Touch Hydrophilic Tip Zebra Guidewire
Ballon Dilator Catheters	Ureteral Balloon Dilator
	Nephrostomy Balloon Dilator
	Transureteroscopic Balloon Dilator
	Transureteroscopic Ureteral Balloon Dilator and Sets With Hydrophilic Tip
	Ureteral Balloon Dilator and Sets With Hydrophilic Tip
	Occlusion Balloon Catheter
Malecot Nephrostomy Catheter And Sets	Malecot Nephrostomy Catheter and Sets
	Re-Entry Malecot Catheter

25 May 2021, Istanbul, Turkey

ücel
Head of Notified Body

Enclosure of the EC Certificate:

Page 3/6

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Nephrostomy Catheter And Sets	Nephrostomy Pigtail Catheter and Sets
	Nephrostomy Pigtail Catheter and Sets with Trocar Needle
	Nephrostomy Pigtail Catheter and Sets with Locking
	Nephrostomy Pigtail Catheter and Sets With Trocar Needle, Locking
	Hydrophilic Multi Purpose Pigtail Drainage Catheter and Sets Locking, with Needle
Nephrostomy Balloon Dilatation Catheter Set	-
Nephrostomy Balloon Dilatation Catheter Kit	-
Intracavitary Hyperthermia Catheter Set	-
Closed Wound Drainage Systems And Accessories	Wound Drainage Sets
	Soft Drains with Drainage Bag
	Wound Drainage Sets with Reservoirs and with Flat Drains
	Flat Drains
	Wound Drainage Reservoir
	Round Silicone Drains
Yankauer Suction Sets And Accessories	Yankauer Suction Sets
	Yankauer Suction Handles
	Aspirator Connecting Tube

25 May 2021, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 4/6

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;

Sterile medical devices

Product Name	Types
Biopsy Punch	-
Airway (Guedel Type)	
Poche Perforator	-
Umbilical Cord Clamp	-
Bacterial Filters	Bacterial Filter
	Hmef Filter
	Hme Filter
	Hepa Filter
	Bacterial Filter
	HMEF Filter- Elite
Smear Brush & Smear Brush Endocervical	Smear Brush
	Smear Brush Endocervical
Karman Cannula	-
Suction Bag & Canister And Accessories	Suction Bags
	Suction Bag Tubes
	Kapkon Connector
Extension Line	
Three Way Stopcock	-
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Threatment Chamber
	Breathing and Anesthesia Circuit Accessories

25 May 2021, Istanbul, Turkey

HEAD OF NOTIFIED BODY

Enclosure of the EC Certificate:

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**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-100, Revision Number: 11**

Concerned medical devices;
Sterile medical devices

Product Name	Types
Arthroscopy Set Y (T.U.R)	Arthroscopy Set Y (T.U.R.)
	Arthroscopy Set with Manual Pressure Pump (T.U.R.)
Blood Gas Syringe With Needle	-
Endometrial Cell Sampler	-
Disposable Oral Swab	-
Sponge Swab	-
Ureteral Stents And Sets	Ureteral Stent and Sets
	Long Term Ureteral Stent and Sets
	Hydrophilic Ureteral Stent and Sets
	Multilenght Ureteral Stent and Sets
	Hydrophilic Multilenght Ureteral Stent and Sets
	Silicone Multilength Ureteral Stents and Sets
	Endopylotomy Stent and Sets
Cutting Electrodes	Cutting Electrodes Single Stem
Enteral Feeding Bag	Single
	Double
Sterile Karman Syringe	Single Valve, Single Valve Set-Sterile
	Double Valve, Double Valve Set-Sterile

Non- Sterile medical Devices

Product Name	Types
Manual Resuscitator	Reusable Manuel Resuscitator
	Disposable Manuel Resuscitator
	Reusable Manuel Resuscitator Sets
	Disposable Manuel Resuscitator Sets

25 May 2021, Istanbul, Turkey

Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-11-100, Revision Number: 11

Concerned medical devices;
 Non-Sterile medical devices

Product Name	Types
Disposable Air Cushion Mask	Neonatal
	Infant
	Pediatric
	Child
	Small Adult
Silicone Mask	Adult
	Neonatal
	Infant
	Pediatric
	Child
Respiratory Masks and Accessories	Small Adult
	Adult
	Oxygen Masks and Accessories
	Nebulizer Set and Accessories
Karman Syringe	High Concentration Oxygen Mask
	Nasal Oxygen Cannula
Suction Bag & Canister And Accessories	Single Valve, Single Valve Set
	Double Valve, Double Valve Set
Breathing And Anesthesia Circuits	Suction Bags
	Suction Canister
	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
CPAP BPAP Masks	Breathing Inhalation- Treatment Chamber
	Breathing and Anesthesia Circuit Accessories
CPAP BPAP Masks	Ora-Nasal
	Nasal

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

25 May 2021, Istanbul, Turkey

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 mütakabil 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 mütakabil 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.



Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyel şirket
Merkez: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO)
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KDV Tescil No: 00627711203 Vergi KN 03502820370 - Hisseli sermaye: € 1.000.000,00 i.v.

Tercüme edilmek üzere bana
dilindeki (S.A.) olan belge
tam ve doğru olarak çevirdiği

YEMİNLİ TERCÜMAN: Mehmet Tur



İda İstemi
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