CERTIFICATE

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

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

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

Muhteşem Gökhan Yücel
Head of Notified Body

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

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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 Hyrophilic 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

Muhteşem Gökhan Yücel
Head of Notified Body

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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

Muhteşem Gökhan Yücel
Head of Notified Body

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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
	HME Filter- Elite
Smear Brush & Smear Brush Endocervical	Smear Brush
	Smear Brush Endocervical
Karman Cannula	-
Suction Bag & Canister And Acccessories	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

Muhteşem Gökhan Yücel
Head of Notified Body

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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 Multilenghth 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

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
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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
	Adult
Silicone Mask	Neonatal
	Infant
	Pediatric
	Child
	Small Adult
	Adult
Respiratory Masks and Accessories	Oxygen Masks and Accessories
	Nebulizer Set and Accessories
	High Concentration Oxygen Mask
	Nasal Oxygen Cannula
Karman Syringe	Single Valve, Single Valve Set
	Double Valve, Double Valve Set
Suction Bag & Canister And Acccessories	Suction Bags
	Suction Canister
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Threatment 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

Münteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
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Kiwa Cermet Italia

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

Sayın

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

Onaylanmış Kuruluş Teyit Mektubu Referansı: CERBO0430223

Sayın İlgili,

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

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

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

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

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

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

Tercüme edilmek üzere bana verilen İN
dilindeki (A5.m.) olan belgeyi TÜRK(
tam ve doğru olarak çevirdiğimi beyan
YEMİNLİ TERCÜMAN:Meyzi Turan Hacıos

ge Sk. Moda İşhanı
110 Kızılay / ANKARA
39 07 Faks: 425 47 69

Kiwa Cermet Italia

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

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

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

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

Tercüme edilmek üzere bana verilen
dilindeki (ASM...) olan belgeyi TÜR
tam ve doğru olarak çevirdiğimi beya
YEMİNLİ TERCÜMAN:Meyzi Turan Hacı

nakşa Sk. Moda İşhanı
21/110 Kızılay / ANKARA

Kiwa Cermet Italia

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

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

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

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

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

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YEMİNLİ TERCÜMAN:Mevzi

ESRA YEMİNLİ TERCÜMAN BÜROSU
nir Cad. Menekşe Sk. Moda İşhanı
. 2. Kat No: 21/110 Kızılay / ANKARA

Kiwa Cermet Italia

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

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

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YEMİNLİ TERCÜMAN:Mevzi Turan H

ASLI

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

Kiwa Cermet Italia

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

Tercüme edilmek üzere bana dilindeki [illegible] olan belg tam ve doğru olarak çevirdiği
YEMİNLİ TERCÜMAN:Meyzi Tur

ESA YEMİNLİ TERCÜMAN BÜROSU
ad. Menekşe Sk. Moda İşhanı
at No: 21/110 Kızılay / ANKARA
[illegible] Fax: 425 47 88

Kiwa Cermet Italia

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

Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koo
Merkez: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO)
Tel. +39.051.4593.111 - Fax +39.051.763.382 - info@kiwacermet.it -
KDV Tescil No: 00627711203 Vergi KN 03502820370 – Hisseli sermay

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tam ve doğru olarak çevirdiğimi b

YEMİNLİ TERCÜMAN: Mevsi Turan H

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

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

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YEMİNLİ TERCÜMAN:Meyzi Turan Ha

enekşe Sk. Moda İşhanı
: 21/110 Kızılay / ANKARA
417 99 87 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, mütekabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
GİRİŞ İĞNELERİ / CHIBA İĞNELERİ	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
TAŞ TUTUCU / PYRAMID TAŞ ÇIKARMA SEPETİ / TAŞ ÇIKARMA SEPETİ ALTI TEL SIFIR UÇ NİTİNOL / TAŞ ÇIKARMA SEPETİ SIFIR UÇ NİTİNOL / HELİKAL TAŞ ÇIKARMA SEPETİ / YASSI TELLİ TAŞ ÇIKARMA SEPETİ / TAŞ ÇIKARMA FORSEPSİ / NİTİNOL PERKÜTAN SEPETİ / AMPLATZ RENAL DİLATÖR VE KILIF SETLERİ / AMPLATZ RENAL KILIFLAR / FASCİAL DİLATÖRLER / FASCİAL DİLATÖR SETLERİ / URETERAL KATETERLER / HİDROFİLİK URETERAL KATETERLER / HİDROFİLİK URETERAL GİRİŞ KATETERİ / İKİ KANALLI URETERAL KATETER / HİDROFİLİK URETERAL GİRİŞ KILIFI VE DİLATÖR SETLERİ / URETERAL DİLATÖR SETLERİ / SUPRAPUBİK KATETER SET POLİÜRETAN / SUPRAPUBİK KATETER SETLERİ SİLİKON-BALONLU / OCEAN TOUCH NİTİNOL HİDROFİLİK UÇLU KILAVUZ TEL / OCEAN NİTİNOL KILAVUZ TELİ /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Tercüme editmek üzere bana
dilindeki (AGA) olan belge
tam ve doğru olarak çevirdiğin
YEMİNLİ TERCUMAN Meyzi Tura

ESRA yeminli tercüman bürosu
Cad. Menekşe Sk. Moda İşhanı
Kat No: 21/110 Kızılay / ANKARA
Tel: 0312 417 00 87 Fax: 425 47 83

Kiwa Cermet Italia

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

Teyit Yazısı Revizyon Tarihçesi

Rev.	Tarih	Aksiyon
00	11.01.2024	İlk Sertifikasyon

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

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

Tercüme edilmek üzere bana veri
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YEMİNLİ TERCÜMAN:Meyzi Turan H

nir Cad. Menekşe Sk. Moda İşhanı
: 2. Kat No: 21/110 Kızılay / ANKARA
Fax: 425 47 83

Kiwa Cermet Italia

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

Esteemed

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

Notified Body Confirmation Letter Reference: CERBO0430223

To whom it may concern,

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

This letter confirms that, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

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

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

Moda İşhanı
Kızılay / ANKARA

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

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

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
M

ıanı
NKARA
47 A3

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

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

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Wound Drainage Sets Soft / Drains With Drainage Bag / Wound Drainage Sets (Mini Type) / Flat Drains / Wound Drainage Sets With Reservoirs And With Flat Drains / Round Drains / Wound Drainage Reservoirs	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Nasal Oxygen Cannula / Oxygen Mask / High Concentration Oxygen Mask / Oxygen Mask Tube / Nebulizer Kit / Nebulizer Set	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Yankauer Suction Handle / Yankauer Suction Set	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Yankauer Suction Connecting Tube	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Biopsy Punch	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Guedel Airway	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Respiratory Exercise Device w/ 3 Ball	IIA	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
HEPA FILTER / BACTERIAL VIRAL FILTER / BACTERIAL VIRAL W/ HME FILTER	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
REUSABLE RESUSCITATOR DEVICE / REUSABLE MANUAL RESUSCITATOR DEVICE SET / DISPOSABLE RESUSCITATOR DEVICE / DISPOSABLE MANUAL RESUSCITATOR DEVICE SETS / SILICON MASKS / INFLATABLE MASK	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL BALLOON DILATOR / TRANSURETEROSCOPIC BALLOON DILATOR / TRANSURETEROSCOPIC BALLOON DILATOR w/ INFLATION DEVICE / URETERAL BALLOON DILATOR and INFLATION DEVICE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
KARMAN SYRINGE SINGLE VALVE, STERILE / KARMAN SYRINGE SINGLE VALVE / KARMAN SYRINGE DOUBLE VALVE,STERILE / KARMAN SYRINGE DOUBLE VALVE / KARMAN SYRINGE SINGLE VALVE SET, STERILE / KARMAN SYRINGE DOUBLE VALVE SET / KARMAN SYRINGE DOUBLE VALVE SET,STERILE / KARMAN SYRINGE SINGLE VALVE SET / KARMAN CANNULA	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SUCTION BAG, NON STERILE / SUCTION BAG / SUCTION CANISTER	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SUCTION BAG TUBE / KAPKON CONNECTOR	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
EXTENSION LINE	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NEPHROFLEX® BALLOON DILATOR / NEPHROFLEX® BALLOON	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Sk. Moda Işhanı
Kızılay / ANKARA

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.

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
BREATHING CIRCUIT EXTENDABLE, STERILE / BREATHING CIRCUIT IPPB, STERILE / BREATHING CIRCUIT COAXIAL, STERILE / BREATHING CIRCUIT TRANSPORT, STERILE / BREATHING CIRCUIT IPPB SEMI CLOSED SYSTEM, STERILE / CATHETER MOUNT CORRUGATED W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT SMOOTHBORE W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT EXTENDED W/ DOUBLE SWIVEL ELBOW, STERILE / CATHETER MOUNT CORRUGATED, STERILE / CATHETER MOUNT SMOOTHBORE, STERILE / CATHETER MOUNT EXTENDED, STERİLE / BREATHING TRACHEOSTOMY CIRCUIT, STERILE / TRACHEOSTOMY CIRCUIT T CONNECTOR, STERILE			
Y IRRIGATION SET / Y-TUR IRRIGATION SET W/ MANUAL PRESSURE PUMP	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
CAMERA COVER	IS	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
ENDOMETRIAL CELL SAMPLER	IS	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
I.V FLOW REGULATOR	IIA	Same	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.
URETERAL STENTS / URETERAL STENT SETS / LONG TERM URETERAL STENTS / LONG TERM URETERAL STENT SETS / HYDROPHILIC URETERAL	IIB	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

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ay / ANKARA
x: 425 47 83

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.

Kiwa Cermet Italia

Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
WIRE / OCEAN NITINOL GUIDEWIRE / HYDROPHILIC NITINOL GUIDEWIRE / HYDROPHILIC NITIONOL SLIPPY GUIDEWIRE / PTFE NITINOL GUIDEWIRE WITH HYDROPHILIC TIP / PTFE GUIDEWIRE / PTFE SUPER STIFF GUIDEWIRE			
NEPHROSTOMY MALECOT CATHETERS / NEPHROSTOMY MALECOT CATHETER SETS / RE-ENTRY MALECOT CATHETERS / NEPHROSTOMY PIGTAIL CATHETERS / NEPHROSTOMY PIGTAIL SETS / HYDROPHILIC PIGTAIL CATHETERS / HYDROPHILIC PIGTAIL CATHETER SETS	IIB	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
CPAP BPAP Masks Ora-Nasal / CPAP BPAP Masks Nasal	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
Enteral Feeding Bag Single / Enteral Feeding Bag Double	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.

Confirmation Letter Revision History

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

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

. Moda İşhanı
Kızılay / ANKARA
Tel: 425 47 83

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

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

05.02.2024

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

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

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

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

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

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

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

I kindly request your information and necessary

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

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

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Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA
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Kep Address: titck@hs01.kep.tr

Tercüme edilmek üzere bana ve dilindeki (.....) olan belgeyi /u tam ve doğru olarak çevirdiğimi YEMİNLİ TERCÜMAN :

. Menekşe Sk. Moda İşhanı
No: 21/110 Kızılay / ANKARA
37 : 417 39 07 Fax: 425 47 83

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

TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI

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

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

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

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

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

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

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

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

Bilgilerinizi ve gereğini rica ederim.

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

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

İzmir Ca
A Blok 2. Ka
Tel: 419 82

Bu belge, güvenli elektronik imza ile imzalanmıştır.
Belge Doğrulama Kodu: 0ZW56ZW56ZW56ak1UZmxXZW56Z1AxYnUy Belge Takip Adresi:https://www.turkiye.gov.tr/saglik-titck-ebys

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CERTIFICATE

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 eight pages.

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3567.08
Date of first issue: 25 July 2011
Date of last issue: 16 July 2020
Revision Number: 10
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.

16 July 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

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: 10

Concerned medical devices;
Sterile medical devices

Product Name	Types
Stone Baskets	Nitinol Helical
	Nitinol Flat Wire
	Nitinol Triprong
	Nitinol Tipless
	Nitinol Percutaneous Basket
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	Ureteral Access Sheat& Dilator Set
	Nottingham Dilator Catheter
	Ureteral Dilators and Sets

16 July 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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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
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
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
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

16 July 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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Sterile medical devices

Product Name	Types
Nephrostomy Balloon Dilatation Catheter Set	30F 15cm
	30F 12cm
Nephrostomy Balloon Dilatation Catheter Kit	30F 15cm
	30F 12cm
Intracavitary Hyperthermia Catheter Set	950151
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
Spirometer Filters	Eliptic Mouth
	Circular Mouth
	Graded Mouth - Cartoon Mouth
	Circular Mouth - Cartoon Mouth
Yankauer Suction Sets And Accessories	Yankauer Suction Sets
	Yankauer Suction Handles
	Aspirator Connecting Tube
Biopsy Punch	230101
	230102
	230103
	230104

16 July 2020, Istanbul, Turkey

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Concerned medical devices;
Sterile medical devices

Product Name	Types
Airway	200101
	200102
	200103
	200104
	200105
	200106
	200107
	200108
	200109
Poche Perforator	150201
Umbilical Cord Clamp	150101
Bacterial Filters	Bacterial Filter
	Hmef Filter
	Hme Filter
	Hepa Filter
	Bacterial Filter
	HMEF Filter- Elite
	HME Filter- Elite
Smear Brush	Smear Brush
	Smear Brush Endocervical

16 July 2020, Istanbul, Turkey

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Concerned medical devices;
Sterile medical devices

Product Name	Types
Karman Cannula	240111
	240112
	240113
	240114
	240115
	240116
	240117
	240118
	240119
Suction Bag & Canister And Acccessories	Suction Bags
	Suction Bag Tubes
	Kapkon Connector
Extension Line	310030
	310045
	310060
	310075
	310090
	310120
	310145
	310200
	320030
	320045
	320060

16 July 2020, Istanbul, Turkey

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Concerned medical devices;
Sterile medical devices

Product Name	Types
Extension Line	320075
	320090
	320120
	320145
	320200
	320210
	325030
	325045
	325060
	325075
	325090
	325120
	325145
	325200
Three Way Stopcock	301001
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Threatment Chamber
	Breathing and Anesthesia Circuit Accessories
Arthroscopy Set Y (T.U.R)	Arthroscopy Set Y (T.U.R.)
	Arthroscopy Set with Manual Pressure Pump (T.U.R.)

16 July 2020, Istanbul, Turkey

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Concerned medical devices;

Sterile medical devices

Product Name	Types
Blood Gas Syringe	210301
	210302
	210321
	210322
Endometrial Cell Sampler	240201
Disposable Oral Swab	490101
Sponge Swab	490104
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 Multilenghth Ureteral Stents and Sets
	Endopylotomy Stent and Sets
Cutting Electrodes	Cutting Electrodes Single Stem

Non- Sterile medical Devices

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

16 July 2020, Istanbul, Turkey

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Concerned medical devices;
Non - Sterile medical devices

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

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

16 July 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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CERTIFICATE

CE Sertifikatas

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100

Mes tokiu būdu deklaruojame, kad patikrinimas pagal žemiau paminėtos pilnos kokybėssistemos draudimą, buvo vykdomas išlaikant nacionalinių įstatymų reikalavimus pagal kuriuos veikiama, perkeliant Medicinos Prietaisų Direktyvos 93/42/ECC Priedą II (Su Sekcijos 4 išimtimi).

Mes sertifikuojame, kad pilnos kokybės draudimo Sistema atitinka minėtos Direktyvos reikiamas nuostatas .

Organizacija:

PLASTI-MED PLASTIK MEDIKAL ÜRÜNLER SANAYI VE TICARET LIMITED SIRKETI

Deri OSB Mahallesi. Yan Sanayi Cad. Nr.:13, Tuzla/Stambulas/Turkija

Produktai apibūdinami priede, kuris yra yra Sertifikato dalis ir sudaro 8 puslapius.

Sertifiktas galioja iki galiojimo datos pabaigos, sėkmingai įvykdžius periodiškus auditus. Prašome, kreiptis į Kiwa dėl detalių.

Ataskaitos numeris: M.3567.08
Pirmo išdavimo data: 2011/07/25
Paskutinio išdavimo data: 2020/07/16
Patikros numeris: 10
Galiojimo data: 2024/05/27

Kiwa Belgelendirme Hizmetleri A.S. patikrino kokybės sistemą, kuri yra ribojama gamintojo suinteresuotais aspektais saugoti ir išlaikyti sterilias sąlygas pagal MDD Priedą II klasei Is prietaisams, apie kuriuos kalba šis sertifikatas, ir nustatė, kad kokybės sistema atitinka MDD Priedo II reikalavimus.

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas **Puslapis 1/8**

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipai**
Akmenų ištraukimo krepšeliai	Nitinolio spiralinis
	Nitinolio plokščios vielos
	Nitinolio trišakis
	Nitinolio be galo
	Nitinolio perkutaninis krepšelis
Urodinaminiai kateteriai ir rinkiniai	Urodinaminis cistometrinis kateteris ir rinkinys
	Hidrofilinis urodinaminis cistometrinis kateteris
	Urodinaminis cistometrinis kateteris ir UPP kateteris
	Hidrofilinis urodinaminis cistometrinis kateteris ir UPP kateteris
Inkstų dilatatoriai ir jų rinkiniai	Amplatz inkstų lapas
	Amplatz inkstų plėstuvas ir lapų rinkinys
	Jungiamojo audinio plėstuvas ir rinkinys
	Perkutaninio trakto plėtimo rinkinys su nefrostominiu plėtimo balionu
	Prisukamas plėstuvas
	Perkutaninio trakto plėtimo rinkinys su Amplatz inkstų plėtimo rinkiniu
Šlapimtakių kateteriai	Dvigubo spindžio šlapimtakių kateteriai
	Šlapimtakių kateteriai
	Hidrofiliniai šlapimtakių kateteriai
Ureteriniai pravedėjai ir dilatatorių rinkiniai	Šlapimtakių prieigos lapas ir plėtiklių rinkinys
	Nottingo plėtimo rinkinys
	Šlapimtakių plėtikliai ir rinkiniai

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas **Puslapis 2/8**

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipai**
IUI kateteriai	IUI kateteriai
	IUI kateterių kaniulės
Suprapubiniai kateteriai ir rinkiniai	Suprapubiniai kateteriai ir rinkiniai
	Silikoniniai suprapubiniai kateteriai ir rinkiniai
Adatos	TLA įvedimo adata
	Pirminio punktavimo adata
	Chiba adata
Nukreipiamosios vielos	Nitinolinės vielos-pravedėjai
	Hidrofilinės nitinolinės vielos-pravedėjai
	Zebra nitinolinės vielos-pravedėjai
	Teflonu dengtos vielos-pravedėjai
Balioniniai plėtimo kateteriai	Ureteriniai balioniniai plėtikliai
	Nefrostominiai balioniniai plėtikliai
	Transureteroskopiniai balioniniai plėtikliai
	Transuretoskopiniai Ureteriniai balioniniai plėtikliai ir rinkiniai su hidrofiliniu dangteliu
	Ureteriniai balioniniai plėtikliai ir rinkiniai su hidrofiliniu dangteliu
	Okliuziniai balioniniai kateteriai
Malecot nefrostominiai kateteriai ir rinkiniai	Malecot nefrostominiai kateteriai ir rinkiniai
	Pakaitiniai Malecot kateteriai
Nefrostominiai kateteriai ir rinkiniai	Nefrostominiai „pigtail“ kateteriai ir rinkiniai
	Nefrostominiai „pigtail“ kateteriai ir rinkiniai su trokar adata
	Nefrostominiai „pigtail“ kateteriai ir rinkiniai su užraktu
	Nefrostominiai „pigtail“ kateteriai ir rinkiniai su trokar adata, užraktu
	Hidrofiliniai daugiafunkciniai „pigtail“ drenavmo kateteriai ir rinkiniai su užraktu ir adata

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas **Puslapis 3/8**

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipas**
Nefrostominiai balioniniai plėtimo rinkiniai	30F 15cm
	30F 12cm
Nefrostominiai balioniniai plėtimo rinkiniai	30F 15cm
	30F 12cm
Vidaus ertmių hipertermijos kateterių rinkiniai	950151
Uždarų žaizdų drenažo sistemos ir priedai	Žaizdų drenažo rinkiniai
	Minkšti drenai su drenažo krepšiu
	Žaizdų drenažo rinkiniai su rezervuarais ir plačiais drenais
	Platūs drenai
	Žaizdų drenažo rezervuaras
	Apvalūs silikono drenai
Spirometriniai filtrai	Elipsinė anga
	Apvali anga
	Graduota anga – multiplikacinė anga
	Apvali anga – multiplikacinė anga
Yankauer atsiurbimo rinkiniai ir priedai	Yankauer atsiurbimo rinkiniai
	Yankauer atsiurbimo rankenos
	Aspiratoriaus jungiamasis vamzdis
Odos biopsijos adatos	230101
	230102
	230103
	230104

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipai**
Orofaringiniai vamzdeliai	200101
	200102
	200103
	200104
	200105
	200106
	200107
	200108
	200109
Kabliukas (Ginekologinis) vaisiaus plėvės pradūrimui	150201
Virkštelės spaustukas	150101
Bakteriniai filtrai	Bakterinis filtras
	Hmef filtras
	Hme filtras
	Hepa filtras
	Bakterinis filtras
	HMEF filtras - rinktinis
	HME filtras - rinktinis
Ginekologinė šluotelė	Ginekologinis šepetėlis
	Ginekologinė šluotelė endocervikalinis

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas **Puslapis 5/8**

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipas**
Karman kaniulės	240111
	240112
	240113
	240114
	240115
	240116
	240117
	240118
	240119
Atsiurbimo maišelis ir indas su priedais	Atsiurbimo maišeliai
	Atsiurbimo indų vamzdeliai
	Kapkon konektorius
Prailginimo linijos	310030
	310045
	310060
	310075
	310090
	310120
	310145
	310200
	320030
	320045
	320060

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipas**
Prailginimo linijos	320075
	320090
	320120
	320145
	320200
	320210
	325030
	325045
	325060
	325075
	325090
	325120
	325145
	325200
Trijų kanalų vožtuvas	301001
Kvėpavimo ir anestezijos kontūrai	Kvėpavimo kontūrai
	Anestezijos kontūrai
	Prailgintojas prie intubacinio vamzdelio
	Kvėpavimo inhaliacija – gydymo kambarys
	Kvėpavimo kontūru priedai
Artroskopijos rinkinys Y (T.U.R)	Artroskopijos rinkinys Y (T.U.R)
	Artroskopijos rinkinys su rankine slėgio pompa (T.U.R)

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas **Puslapis 7/8**

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Sterilūs medicinos prietaisai

Produkto pavadinimas	**Tipas**
Kraujo dujų švirkštai	210301
	210302
	210321
	210322
Endometrumo ląstelių mėginių ėmiklis	240201
Vienkartinis burnos tamponas	490101
Kempinės tamponas	490104
Šlapimtakių stentai ir rinkiniai	Šlapimtakių stentai ir rinkiniai
	Ilgo veikimo šlapimtakių stentai ir rinkiniai
	Hidrofiliniai šlapimtakių stentai ir rinkiniai
	Daugiailgiai šlapimtakių stentai ir rinkiniai
	Hidrofiliniai daugiailgiai šlapimtakių stentai ir rinkiniai
	Silikoniniai daugiailgiai šlapimtakių stentai ir rinkiniai
	Endopilotomijos stentai ir rinkiniai
Pjovimo elektrodai	stentai ir rinkiniai vienastiebiai

Nesterilūs medicinos prietaisai

Produkto pavadinimas	**Tipai**
Rankinė gaivinimo sistema	Daugkartinė rankinė gaivinimo sistema
	Vienkartinė rankinė gaivinimo sistema
	Daugkartinės rankinės gaivinimo sistemos rinkiniai
	Vienkartinės rankinės gaivinimo sistemos rinkiniai

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

CE Sertifikato Priedas

Pilnos Kokybės Draudimo Sistema pagal

Medicinos Prietaisų Direktyvą 93/42/EEC Priedas – II Sekcija 3

Sertifikato numeris: 1984-MDD-11-100, Patikrinimo numeris: 10

Rūpimi medicinos prietaisai:
Nesterilūs medicinos prietaisai

Produkto pavadinimas	**Tipas**
Vienkartinės pripučiamos deguonies kaukės	Naujagimis
	Kūdikis
	Vaikas
	Vyresnis vaikas
	Jaunas suaugęs
	Suaugęs
Silikoninės kaukės	Naujagimis
	Kūdikis
	Vaikas
	Vyresnis vaikas
	Jaunas suaugęs
	Suaugęs
Kvėpavimo kaukės ir priedai	Deguonies kaukės ir priedai
	Purkštuvų rinkiniai ir priedai
	Aukštos koncentracijos deguonies kaukė
	Nosies deguonies kaniulė
Karman švirkštai	Vieno vožtuvo
	Dviejų vožtuvų
Atsiurbimo maišeliai ir indai ir priedai	Atsiurbimo maišeliai
	Atsiurbimo indai
Kvėpavimo ir anestezijos kontūrai	Kvėpavimo grandinės
	Anestezijos grandinės
	Kateterio stovas
	Kvėpavimo inhaliacija – gydymo kambarys
	Kvėpavimo ir anestezijos grandinės priedai

Kiwa Belgelendirme Hizmetleri A.S. yra notifikuojanti įstaiga pagal medicinos prietaisųTarybos Direktyvą 93/42/EEC su identifikacijos numeriu: 1984

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel

Notifikuotos įstaigos vadovas

CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-11-104

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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

Products: Pediatric Urine Bag, Vaginal Speculum, Camera Cover, Endotrakeal Stylet, Spirometer Filter Accessories, Vomit Bag, Respiratory Exercise Device

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

Report Number:	M.3567.08
Date of first issue:	26 July 2011
Date of last issue:	26 July 2019
Revision Number:	05
Expiry Date:	27 May 2024

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

26 July 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-11-104, Revision Number: 05

Concerned medical devices;

Product Name	Types	Class
Pediatric Urine Bag	Pediatric Urine Bag Male	Is & Im
	Pediatric Urine Bag Female	Is & Im
Vaginal Speculum	Large, Medium, Screw Medium	Is
Camera Cover	170101	Is
Endotrakeal Stylet	04-06-08-10-12-16 CH	Is
Spirometer Filter Accessories	Spirometer Mouth - 22-30-33 mm	Is
Vomit Bag	950021	Im
Respiratory Exercise Device	Three Balls	Im

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

26 July 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CE sertifikatas
Pilna kokybės užtikrinimo sistema pagal Medicinos priemonių direktyvos 93/42/EEB V priedą
Sertifikato numeris: 1984-MDD-11-104

Pareiškiame, kad buvo atliktas patikrinimas, laikantis tarptautinių įstatymų reikalavimų, pagal kuriuos subjektu tampa pasirašytas dokumentas, perkeliant medicinos priemonių direktyvos 93/42/EEB V priedą. Patvirtiname, kad produkcijos kokybės sistema atitinka minėtų teisės aktų atitinkamas nuostatas.

Įmonė:

PLASTI-MED PLASTIK MEDICAL ÜRÜNLER SANAYI VE TICARET LIMITED SIRKETI

Deri OSB Mahallesi Yan Sanayi Cad. Nr: 13 Tuzla/Istanbulas/Turkija

Produktai: vaikiški šlapimo maišeliai, vaginaliniai skėtikliai, užvalkalai kamerai, endotrachėjiniai stiletai, spirometro filtro priedai, vėmimo maišeliai.

Produktai yra surašyti priede, kuris yra šio sertifikato dalis ir susideda iš 1 lapo.
Šis sertifikatas galioja iki nustatytos datos, remiantis periodiškai atliekamo audito sėkmingu įvykdymu. Prašome susisiekti su Kiwa dėl detalių.

Pranešimo numeris:	M. 3567.08
Pirmo leidimo data:	2011 m. liepos 26 d.
Paskutinio leidimo data:	2019 m. liepos 26 d.
Peržiūros Nr:	05
Galioja iki:	2024 m. gegužės 27 d.

Kiwa Belgelendirme Hizmetleri A.S. patikrino kokybės sistemą, skirtą tik gamybos aspektams, susijusiems su prietaisų atitiktimi Im klasės prietaisų metrologiniams reikalavimams ir sterilių sąlygų laikymuisi bei palaikymui pagal MDD V priedą, skirtą prietaisų, kuriems taikomas šis sertifikatas, ir nustatė, kad kokybės sistema atitinka taikomus MDD V priedo reikalavimus.

2019 m. liepos mėn. 26d, Istanbulas, Turkija

/Parašas/
Muhtesem Gokhan Yucel
Notifikuotosios įstaigos vadovas

Kiwa Belgelendirme A.S.
ITOSB 9 Cad. Nr. 15, Tepeoren, Tuzia, Istanbulas, Turkija
Tel.:+90 216 593 25 75, Fax.:+90 216 593 25 74
Web:www.kiwa.com.tr, e-mail: posta@kiwa.com.tr

CE sertifikato priedas: **Puslapis 1 /1**
produkcijos kokybės užtikrinimo sistema pagal
medicinos prietaisų direktyvos 93/42/EB V- priedą
Sertifikato numeris: 1984-MDD-11-104, Peržiūros numeris: 05

Susijusios medicininės priemonės;

Produkto pavadinimas	Tipai	Klasė
Vaikiški šlapimo maišeliai	Vaikiškas šlapimo maišelis (vyr.)	Is ir Im
	Vaikiškas šlapimo maišelis (mot.)	Is ir Im
Vaginalinis skėtiklis	Didelis, vidutinis, vidutinis užsukamas	Is
Užvalkalas kamerai	170101	Is
Endotrachėjiniai stiletai	04-06-08-10-12-16 CH	Is
Spirometro filtro priedai	Burnos spirometras – 22-30-33 mm	Is
Vėmimo maišai	950021	Im

Kiwa Belgelendirme Hizmetleri A.S. yra notifikuotoji įstaiga pagal medicinos prietaisų Tarybos direktyvą 93/42/EEB, kurių identifikavimo numeris: 1984

2019 m. liepos mėn. 26d, Istanbulas, Turkija */Parašas/*
Muhtesem Gokhan Yucel
Notifikuotosios įstaigos vadovas

Kiwa Belgelendirme A.S.
ITOSB 9 Cad. Nr. 15, Tepeoren, Tuzia, Istanbulas, Turkija
Tel.:+90 216 593 25 75, Fax.:+90 216 593 25 74

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

POLY MEDICURE LIMITED
HSIIDC Industrial Area, Ballabhgarh
Plot No. 104-105, Sector-59
121004 FARIDABAD, HARYANA
INDIA

Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
	TPS3023_AR	keyur.baruwala@tuvsud.com	2024-05-26	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 041938 0010 Rev. 00

Reference: TPS3023_AR

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 (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 and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: IN-MF-000003380

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

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

If 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 041938 0010 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-18

TÜV SÜD Product Service GmbH
Medical and Health Services

Project Handler ( )

TÜV SÜD Product Service GmbH
Medical and Health Services

Application Reviewer

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 1 **IV Cannula / Catheter with/without Safety feature** **Basic UDI-DI: 890209510001CY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 2 **Infusion Sets** **Basic UDI-DI: 890209514001DU**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 3 **Burette Infusion sets** **Basic UDI-DI: 890209514500EK**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 4 **Flow Regulators** **Basic UDI-DI: 890209513100DQ**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 5 **Extension line** **Basic UDI-DI: 890209513180EG**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 6 **CVP Manometers** **Basic UDI-DI: 890209513350EH**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 7 **Stop cocks with/without extension line** **Basic UDI-DI: 890209513001DM**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 8 **Needle free connectors with/without extension line** **Basic UDI-DI: 890209513057EG**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 9 **Scalp Vein (Winged Infusion Set) with/without safety feature** **Basic UDI-DI: 890209513510EF**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 10 **Manifolds with/without extension line** **Basic UDI-DI: 890209513710ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 11	☒ Class IIa	☒ N/A	☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Transfusion Pump Set **Basic UDI-DI: 890209570150FL**			Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 12 **Blood collection set with/without safety features** **Basic UDI-DI: 890209588290J8**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 13 **Transfusion Sets (BT Set)** **Basic UDI-DI: 890209570090FT**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 14 **Closed Wound Suction Unit** **Basic UDI-DI: 890209590050G5**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 15 **Yankaur Suction Set (Suction tube and/or Handle)** **Basic UDI-DI: 890209590140G7**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 16 **Thoracic Drainage Catheters with/without Trocar** **Basic UDI-DI: 890209590080GE**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 17 **Redon Drainage Tubes** **Basic UDI-DI: 890209590060G8**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 18 **Abdominal Drainage Set** **Basic UDI-DI: 890209590110FW**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 19 **Under Water Sealed Drainage System** **Basic UDI-DI: 890209590120FZ**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 20 **Female catheters** **Basic UDI-DI: 890209530060E6**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 21 **Nelaton catheters** **Basic UDI-DI: 890209530010DP**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 22 **Foley Balloon Catheter**	☒ Class IIa	☒ N/A	☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Basic UDI-DI: 890209530303E9			Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 23 **Irrigation Set** **Basic UDI-DI: 890209530520EK**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 24 **Nasogastric Feeding tubes with/without guidewires (Single & Dual port)/Levin's Tube** **Basic UDI-DI: 890209540301EG**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 25 **Ryle's Tubes** **Basic UDI-DI: 890209540001DZ**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 26 **Feeding Bags** **Basic UDI-DI: 890209540600EV**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 27 **Mucus Extractor with/without bacterial Filter** **Basic UDI-DI: 890209540350EV**	☒ Class IIa |	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 28 **Suction Catheter** **Basic UDI-DI: 890209520010DC**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 29 **Nasal Oxygen Catheter/ Cannula** **Basic UDI-DI: 890209520020DF**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 30 **Oxygen Catheters** **Basic UDI-DI: 890209520060DT**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 31 **Endotracheal Tube with Cuff / Without cuffed / Reinforced** **Basic UDI-DI: 890209520150DV**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 32 **Catheter Mount** **Basic UDI-DI: 890209520180E6**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 33 **Oxygen Mask** **Basic UDI-DI: 890209520115DT**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 34 **Nebulizer Mask** **Basic UDI-DI: 890209520111DK**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 35 **Venturi Mask** **Basic UDI-DI: 890209520120DL**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 36 **Blood Line Set** **Basic UDI-DI: 890209570155FW**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 37 **AV Fistula Needle with/without safety features** **Basic UDI-DI: 890209590030FX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 38 **Peritoneal Dialysis Catheter Kit** **Basic UDI-DI: 890209590350GL**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 39 **Luer caps** **Basic UDI-DI: 890209513353EP**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 40 **Stomach Tubes** **Basic UDI-DI: 890209540480FB**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 41 **Guedel Airways** **Basic UDI-DI: 890209520050DQ**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 42 **Peritoneal Dialysis Transfusion Set** **Basic UDI-DI: 890209590360GP**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 43 **Umbilical Cord Clamp** **Basic UDI-DI: 890209590220G6**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 44	☒ Class Is	☒ N/A	☒ Certification as follows:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Urine Collection Bags with/without volume meter **Basic UDI-DI: 890209530101DT**			Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 45 **Trans Urethral Resection Set (TUR Set)** **Basic UDI-DI: 890209530300E3**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 46 **Sterile Bottle caps** **Basic UDI-DI: 890209590286H4**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 47 **Stylet (Obturators)** **Basic UDI-DI: 890209513080EB**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 48 **Huber Infusion set with/without safety features** **Basic UDI-DI: 890209595010GU**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 49 **Over The Needle (OTN) Catheter** **Basic UDI-DI: 890209513440EK**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 50 **Arterial Cannula with/without Safety features** **Basic UDI-DI: 890209513426ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 51 **Mini-midline catheter (Peripheral Catheter)** **Basic UDI-DI: 890209513535EX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 52 **Blood Collection Needle & Holder** **Basic UDI-DI: 890209588110H8**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 53 **Vial Access Spike** **Basic UDI-DI: 890209513068EM**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123
Device 54 **Rectal Catheter** **Basic UDI-DI: 890209530040DY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1S 041938 0003 Rev. 00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 55 **HPVD Bottle with /without extension line and trocar** **Basic UDI-DI: 890209590500GF**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 56 **Feeding tubes with/ without Guidewires** **Basic UDI-DI: 890209540050EE**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123
Device 57 **Blood Bag (Transfer Bag)** **Basic UDI-DI: 890209570050FF**	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 041938 0007 Rev. 00; NB# 0123

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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 Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-04-18	TSSA/MHS/2024/15 / TPS3023_G10	Initial issue

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
	TPS3025_G10	keyur.baruwala@tuvsud.com		2024-03-12	1 of 6

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 105485 0010 Rev. 00

Reference: TPS3025_G10

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 (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 and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: IN-MF-000003380

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 TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

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

If 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.

The transition timelines in accordance Article 120 (3) of MDR 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, 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 (except 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, 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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 105485 0010 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-13

TÜV SÜD Product Service GmbH
Medical and Health Services

Bardwala
Project Handler (PH)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias
Application Reviewer

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 1 **IV Cannula / Catheter with/without Safety feature** **Basic UDI-DI: 890209510001CY**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 2 **Infusion Sets** **Basic UDI-DI: 890209514001DU**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 3 **Flow Regulators** **Basic UDI-DI: 890209513100DQ**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 4 **Stop cocks with/without extension line** **Basic UDI-DI: 890209513001DM**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 5 **Prefilled Syringe with 0.9% Saline Solution** **Basic UDI-DI: 890209590315GJ**	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 6 **Arterial Cannula with/without Safety features** **Basic UDI-DI: 890209513426ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 7 **Manifolds with/without extension line** **Basic UDI-DI: 890209513710ER**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 8 **Mini-midline catheter (Peripheral Catheter)** **Basic UDI-DI: 890209513535EX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 9 **Blood Collection Needle & Holder** **Basic UDI-DI: 890209588110H8**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 10 **Endotracheal Tube - plain/Cuffed/Reinforced**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Basic UDI-DI: 890209520150DV			
Device 11 **AV Fistula Needle with/without safety features** **Basic UDI-DI: 890209590030FX**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 12 **Dialyzer (Dialysis Filter)** **Basic UDI-DI: 890209590365GZ**	☒ Class IIb	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 13 **Disinfecting Port Protector** **Basic UDI-DI: 890209590309GP**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 105485 0007 Rev. 00; NB# 0123
Device 14 **Vial Access Spike** **Basic UDI-DI: 890209513068EM**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 105485 0008 Rev. 00; NB# 0123
Device 15 **Transfer Spike** **Basic UDI-DI: 890209590314GG**	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G1S 105485 0008 Rev. 00; NB# 0123

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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 Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-13	TPS3025_G10	Initial issue

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

Product Service

EC Certificate

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

No. G1 041938 0007 Rev. 00

Manufacturer:

POLY MEDICURE LIMITED
Plot No. 104-105, Sector-59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
INDIA

Product Category(ies):

IV Cannula/ Catheter with / without Safety Features, Infusion Sets, Burette Infusion Sets, Flow Regulators, Extension Lines, Luer Caps, Stylet (Obturators), CVP Manometers, Stop cock with/without extension line, Needle free connectors with/without extension line, Scalp vein (Winged Infusion) Set (with / without safety features), Insulin Syringe, Huber Infusion set with / without safety features, Over the Needle (OTN) Catheter, Arterial Cannula with/without Safety Features, Manifolds with/without Extension line, Mini-midline Catheter (Peripheral catheter), Transfusion Pump Set, Luer Adaptors, Blood Bags, Blood Collection Set with / without Safety Features, Blood Collection Needle & Holder, Transfusion Sets (BT Sets), Closed Wound Suction Unit, Yankaur Suction Set (Suction tube and/or Handle), Thoracic Drainage Catheter (with/without Trocar), Redon Drainage Tube, Abdominal Drainage Set, Under Water Seal Drainage System, Female catheter, Nelaton catheter, Foley Balloon Catheter, Irrigation Set, Levins tube, Infant Feeding Tube, Ryle's Tube, Stomach Tube, Umbilical Catheter, Feeding Bag, Mucus Extractor with/without Bacterial Filter, Suction Catheter, Nasal Oxygen Catheter/ Cannula, Oxygen Catheter, Guedel Airways, Endotracheal Tubes (Plain, Cuffed, Reinforced), Catheter Mount, Oxygen Mask, Nebulizer Mask, Venturi Mask, Blood Line Set, Fistula Needle with / without Safety features, Peritoneal Dialysis Transfusion Set, Peritoneal Dialysis Catheter Kit, High Pressure Vacuum Drainage Bottle.

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

Report No.: IND2019081_CN

Valid from: 2020-06-17
Valid until: 2024-05-26

Date, 2020-06-17

Christoph Dicks
Head of Certification/Notified Body

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

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

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

Product Service

CE SERTIFIKATAS
Pilnos kokybės užtikrinimo sistema
Pagal direktyvą 93/42/EEC medicininių prietaisų (MDD), priedas II išskyrus (4)
(Prietaisai IIa, Iib arba III klasės)
Nr. G1 041938 0007 Rev. 00

Gamintojas: **POLY MEDICURE LIMITED**
Plot Nr. 104-105, sektorius -59
HSIIDC Industrial Area, Ballabhgarh
Faridabad, Haryana 121004
Indija

Produktų kategorijos: Intraveniniai kateteriai Cannula/ Kateteriai su/be saugumo funkcijomis, infuzijos rinkiniai, biuretės infuzijos rinkiniai, srauto reguliatoriai, prailginimo linijos, Luer kamšteliai, stiletai, CVP monometrai, Stop cock su/be prailginimo linija, be adatos konektoriai su/be prailginimo linija, venos peiliukai (su sparneliais Infuzijos) rinkiniai (su/be saugumo funkcijomis), insulininis švirkštas, Huberio Infuzijos rinkiniai su//be saugumo funkcijomis, kateteriai (OTN), arterinės kaniulės su/be saugumo funkcijomis, kolektoriai su/be prailginimo linija, mini kateteriai (Periferiniai kateteriai), transfuzijos pompos rinkiniai, Luer adapteriai, kraujo maišai, kraujo rinkimo rinkiniai su/be saugumo funkcijomis, kraujo rinkimo adatos ir laikikliai, transfuzijos rinkiniai, uždaros atsiurbimo sistemos, Yankauer siurbimo rinkiniai (atsiurbimo vamzdelis ir/arba su rankena), torakaliniai kateteriai (su/be trokaro), Redon drenažo vamzdelis, pilvo drenažo rinkinys, sandarus vandeniui drenažo sistema, šlapimo moteriški kateteriai, Nelaton kateteriai, Foley balionėlio tipo kateteriai, irigacijos rinkiniai, Levino vamzdeliai, kūdikių maitinimo vamzdeliai, Rylės vamzdeliai, skrandžio zondai, umbilikaliniai kateteriai, maitinimo maišeliai, atsiurbėjai su talpa su/be bakterinio filtro, atsiurbimo kateteriai, nosies/deguonies kateteriai/kaniulės, deguonies kateteriai, Guedelio kvėpavimo takai, endotrachėjiniai vamzdeliai, burnos kateteriai, deguonies kaukė, purkštuvo kaukė, Venturi kaukė, kraujo linijų rinkiniai, Fistula adatos su/be saugumo funkcijomis, pilvaplėvės dializės, transfuzijos rinkiniai, pilvaplėvės dializės kateterio rinkiniai, aukšto slėgio drenažo buteliai.

Sertifikato įstaiga TUV SUD produktų serviso įmonė deklaruoja, kad minėtas gamintojas atitinka gamintojo kokybės užtikrinimo sistemos dizaino, gamybos ir galutinio inspekcijos atitinkamai produktų kategorijas pagal MDD priedą II. Ši kokybės užtikrinimo sistema tvirtina pagal šios direktyvos reikalavimus ir yra periodiškai stebima. III prietaisų klasės reklamai pagal papildomą priedą II (4) sertifikatas yra privalomas.
Žiūrėti taip pat sekančiai.

Ataskaitos nr.: IND2019081_CN

Galioja nuo: 2020-06-17
Galioja iki: 2024-05-26

Data 2020-06-17

/ *parašas*/
Christoph Dicks
Vadovas sertifikuotos/notifikuotos įstaigos

EU Quality Management System Certificate

Certificate no.:	Final Assessment Report No.:	Effective date:	Expiry date:
0521GB448231026	0521AU35F	2023-10-26	2026-11-04

This is to certify that the quality system of

Primed Halberstadt Medizintechnik GmbH

Straße des 20. Juli 1, 38820 Halberstadt, Germany

SRN: DE-MF-000004967

for design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

has been assessed and found to comply with respect to:

The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date:
Hamburg, 2023-10-26

For the issuing office:
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

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

Lorenz
Chief Certification

Certificate no.: 0521GB448231026
Place and date: Hamburg, 2023-10-26

Sites covered by this certificate

Primed Halberstadt Medizintechnik GmbH, Straße des 20. Juli 1, 38820 Halberstadt, Germany

Primed Halberstadt Medizintechnik GmbH (Verwaltung), Domplatz 34, 38820 Halberstadt, Germany

Primed Halberstadt Medizintechnik GmbH, Am Bahndamm 11, 38820 Halberstadt, Germany

Certificate no.: 0521GB448231026
Place and date: Hamburg, 2023-10-26

Products covered by this certificate

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

Category	Class	Medical devices/groups of
MDN 1202	Is	Non-active, non-implantable devices for administration, channelling and removal of substances, including devices for dialysis

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDN 1214	R040102	Ventilation filters, antibacterial and antiviral, moisturizer
MDN 1214	R040101	Antibacterial and Antiviral Respiratory Filters
MDN 1214	R900602	Phonation valves for tracheostomy
MDN 1214	R040201	Tracheostomy humidifiers
MDN 1202	G020301	Rectal Tubes
MDN 1202	A060203	Pleural Drainages with valve and kits
MDN 1202	A060101	Vacuum and gravity drainage systems

Class IIb medical devices

For placing on the market of class IIb medical devices covered by this certificate, an additional EU Type Examination Certificate according to Annex X of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	EMDN code	Medical devices/groups of medical devices
MDN 1201	R010501	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED
MDN 1201	R010502	TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
MDN 1201	R010503	TRACHEOSTOMY INNER CANNULAS

Intended purpose

Tracheostomy tubes are used to keep open a tracheostoma and enable the patient to breathe. Some versions allow phonation and, as a result, speech.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2375149-1

Manufacturer: **Xiamen Compower Medical Tech. Co., Ltd.**
Unit 301, No.16, Xianghong Road,
Xiang'an Torch Industrial Zone,
361101 Xiamen
P.R. China

EUDAMED Single Registration No.: CN-MF-000011703

Products: Products of class IIa:
R030101 - VENTILATION MASKS
R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
R030201 - VENTILATION BALLOONS
R030202 - MANUALLY OPERATED VENTILATION BALLOONS

Authorised representative(s): Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-10-13

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10920784-120

Effective date: 2023-10-13

Expiry date: 2028-10-12

Issue date: 2023-10-13

TÜV Rheinland LGA Products GmbH ... TÜVRheinland ... Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road,
Xiang'an Torch Industrial Zone,
361101 Xiamen
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date October 13, 2023

Application for: QMS
Certificate No. : HZ 2375149-1
Requirement : REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Dear Madame or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. HZ 2375149-1.

Best regards,

Wenxiang Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 16, 2024

Shandong Ruyue Medical Technology Co., Ltd.
North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City,
256600 Shandong,
P.R. China

Notified Body Confirmation Letter
Reference. : 190156518

To whom it may concern,

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

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Shandong Ruyue Medical Technology Co., Ltd.
North of Xinwu Road, West of Gaojiu Road, High-Tech Industrial Development Zone, Binzhou City,
256600 Shandong,
P.R. China
SRN Number: CN-MF-000041139

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 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Certification body

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
Device name: Infusion Sets for Single Use with Needle **Basic UDI-DI:** 697357642RYSYX4	Class IIa	N/A	Certificate #: DD 2265676-1 NB#: 0197
Device name: Sterile Hypodermic Syringes for Single Use with Needle **Basic UDI-DI:** 697357642RYZSXD	Class IIa	N/A	Certificate #: DD 2265676-1 NB#: 0197
Device name: Transfusion Sets for Single Use with Needle **Basic UDI-DI:** 697357642RYSXX2	Class IIa	N/A	Certificate #: DD 2265676-1 NB#: 0197
Device name: Disposable Surgical Gown **Basic UDI-DI:** 697357642RYSSY2H	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 2265676-1 NB#: 0197

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
Device name: Surgical Mask **Basic UDI-DI:** 697357642RYKZWE	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 2265676-1 NB#: 0197
Device name: Disposable Medical Protective Clothing **Basic UDI-DI:** 697357642RYFHUT	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 2265676-1 NB#: 0197
Device name: Surgical Gauze Dressing **Basic UDI-DI:** 697357642RYSBVN	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 2265676-1 NB#: 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/16	190156518	Initial issue

EU Quality Management System Certificate

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

MDR 752387 R000

Manufacturer: Teleflex Medical Inc.

Address:
3015 Carrington Mill Blvd.
Morrisville
North Carolina
27560
USA

Single Registration Number: US-MF-000023660

EU Authorised Representative: Teleflex Medical

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Scope: See attached **Device Schedule**

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

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-02-14**

Current Issue Date: **2024-01-19**

Starting Validity Date: **2024-01-19**

Expiry Date: **2028-02-13**

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EU Quality Management System Certificate

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

MDR 752387 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Weck® Metal Ligating Clips	See MDR 752390
Hem-o-lok® Polymer Ligating Clips	See MDR 752395
Deknatel® Pledgets	See MDR 752399

Class III, Non-Implantable	Intended purpose
Disposable Aortic Punch	See MDR 752405

Class IIb, Implantable, Well-established technologies	Intended purpose
Polyethylene Nonabsorbable Surgical Sutures	Devices are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

First Issue Date: **2023-02-14**

Current Issue Date: **2024-01-19**

Starting Validity Date: **2024-01-19**

Expiry Date: **2028-02-13**

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EU Quality Management System Certificate

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

MDR 752387 R000

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

Device(s)	Risk Classification
Laparoscopic Access Ports	Class IIa, Non-Implantable
Bladeless Obturators	Class IIa, Non-Implantable
Minimally Invasive Surgery Forceps	Class IIa, Non-Implantable
Skin Staplers	Class IIa, Non-Implantable
Fascial Closure System	Class IIa, Non-Implantable
Skin Staple Remover	Class Is
Suture Guide	Class Is
Sterile Mucosal Atomization Device	Class Is
Non-Sterile Mucosal Atomization Device	Class Im
Multiple Clips Applicators, Reusable	Class Ir
Clip Removal Surgical Forceps, Reusable	Class Ir
Metal Cartridge Base, Reusable	Class Ir

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

First Issue Date: **2023-02-14**

Current Issue Date: **2024-01-19**

Starting Validity Date: **2024-01-19**

Expiry Date: **2028-02-13**

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EU Quality Management System Certificate

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

MDR 752387 R000

Certificate History

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

Date	Reference Number	Action
2023-02-14	3479191	Issued
2023-07-14	3911009	Supplemented – Addition of Deknatel® Pledgets. Supplemented – Addition of generic device group Polyethylene Nonabsorbable Surgical Sutures. Supplemented – Addition of device categories Multiple Clips Applicators, Reusable, Clip Removal Surgical Forceps, Reusable, and Metal Cartridge Base, Reusable.
2023-08-30	30004384	Supplemented – Addition of Minimally Invasive Surgery Forceps
Current	30062015	Supplemented – Addition of Laparoscopic Access Ports and Bladeless Obturators

First Issue Date: **2023-02-14**

Current Issue Date: **2024-01-19**

Starting Validity Date: **2024-01-19**

Expiry Date: **2028-02-13**

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EU DECLARATION OF CONFORMITY

Legal Manufacturer	Name: Teleflex Medical Inc. Address: 3015 Carrington Mill Blvd Morrisville, NC 27560 USA Single Registration Number (SRN): US-MF-000023660
Authorized Representative	Name: Teleflex Medical Address: IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland Single Registration Number (SRN): IE-AR-000015869
Notified Body	Name: BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Identification Number: NB 2797

Product Name	Product Classification	Classification Rule	Conformity Assessment Route (s)	Certificate(s) No
Weck™ Hem-o-lok™ Polymer Ligating Clip Appliers and Removers	Class I reusable surgical instruments	Rule 6	Annex IX	MDR 752387

Teleflex Medical Inc. declares that the documented product(s) meets the provisions of Regulation (EU) 2017/745. This declaration is made in accordance with Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation, on the basis of the listed CE Certificate issued by BSI Group The Netherlands B.V. for aspects relating to the reuse of the device. This declaration is issued under the sole responsibility of Teleflex Medical Inc. and authorizes Teleflex Medical Inc. to affix the CE-marking to the products listed herein.

Intended Purpose: Weck® Hem-o-lok® Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok® Non-absorbable Polymer Ligating Clips. Weck® Hem-o-lok® Endoscopic Ligating Clip Appliers and Weck® Hem-o-lok® Take Apart Endoscopic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok Non-absorbable Polymer Ligating Clips through specific sized trocar cannulas (5 mm, 10 mm, or larger). Other ligation clips cannot be used with these appliers.

Weck® Hem-o-lok® Ligating Clip Removers, Weck® Hem-o-lok® Endoscopic Ligating Clip Removers, and Weck® Hem-o-lok® Take Apart Endoscopic Ligating Clip Removers are indicated for use as removal devices for Hem-o-lok Ligating Clips. These removers cannot be used with other ligation clips.

Basic UDI-DI	Product Name	Product Code	EMDN/ CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
0801902000000 0000000010JT	Weck™ Hem-o-lok™ M Ligating Clip Applier, Curved Jaw, 8” (20 cm)	544113	L020801	Tecomet Inc. 5307 95th Ave Kenosha, WI 53144 USA	08/2000
0801902000000 0000000010JT	Weck™ Hem-o-lok™ M Ligating Clip Applier, Right Angled Jaw, 11” (28 cm)	544114	L020801		09/2001
0801902000000 0000000010JT	Weck™ Hem-o-lok™ M Ligating Clip Applier, Curved Jaw, 11” (28 cm)	544115	L020801		08/2000
0801902000000 0000000010JT	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Curved Jaw, 8” (20 cm)	544170	L020801		11/2001
0801902000000 0000000010JT	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Curved Jaw, 11” (28 cm)	544171	L020801		10/2000
0801902000000 0000000010JT	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Right Angled Jaw, 11” (28 cm)	544172	L020801		09/2001
0801902000000 0000000010JT	Weck™ Hem-o-lok™ L Ligating Clip Applier, 70° Jaw, 11” (28 cm)	544179	L020801		10/1999
0801902000000 0000000010JT	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 8” (20 cm)	544180	L020801		11/2001

Basic UDI-DI	Product Name	Product Code	EMDN/ CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
0801902000000 0000000010JT	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 11” (28 cm)	544181	L020801		03/1999
0801902000000 0000000010JT	Weck™ Hem-o-lok™ L Conduit Ligating Clip Applier, 70° Angle Jaw, 11” (28 cm)	544182	L020801		05/2004
0801902000000 0000000010JT	Weck™ Hem-o-lok™ XL Ligating Clip Applier, Curved Jaw, 11” (28 cm)	544191	L020801		02/2004
0801902000000 0000000010JT	Weck™ Hem-o-lok™ XL Ligating Clip Applier, 70° Angled Jaw, 11” (28 cm)	544192	L020801		02/2004
0801902000000 0000000012JX	Weck™ Hem-o-lok™ ML Endoscopic Clip Applier, 32.5 cm	544965	L020802	Tecomet Inc. 5307 95th Ave Kenosha, WI 53144 USA	02/2002
0801902000000 0000000012JX	Weck™ Hem-o-lok™ ML Endoscopic Clip Applier, 45 cm	544965L	L020802		11/2009
0801902000000 0000000012JX	Weck™ Hem-o-lok™ XL Endoscopic Clip Applier, 33 cm	544990	L020802		05/2003
0801902000000 0000000012JX	Weck™ Hem-o-lok™ XL Endoscopic Clip Applier, 45 cm	544990L	L020802		11/2009
0801902000000 0000000012JX	Weck™ Hem-o-lok™ L Endoscopic Clip Applier, 33 cm	544995	L020802		03/1999
0801902000000 0000000012JX	Weck™ Hem-o-lok™ L Endoscopic Clip Applier, 45 cm	544995L	L020802		11/2009
0801902000000 0000000011JV	Weck™ Hem-o-lok™ M Take Apart 5 mm Endoscopic M Clip Applier	544945T	L020802	Koscher & Wuertz Einsteinstrasse 7 Spaichingen, DE-BW Germany 78549	11/2018
0801902000000 0000000011JV	Weck™ Hem-o-lok™ ML Take Apart 5 mm Endoscopic ML Clip Applier	544965T	L020802		04/2007
0801902000000 0000000011JV	Weck™ Hem-o-lok™ ML Take Apart Endoscopic ML Clip Applier, 20 Degree	544965T20	L020802		06/2010

Basic UDI-DI	Product Name	Product Code	EMDN/ CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
0801902000000 0000000011JV	Weck™ Hem-o-lok™ XL Take Apart 10 mm Endoscopic XL Clip Applier	544990T	L020802		04/2007
0801902000000 0000000011JV	Weck™ Hem-o-lok™ XL Take Apart Endoscopic XL Clip Applier, 20 Degree	544990T20	L020802		06/2010
0801902000000 0000000011JV	Weck™ Hem-o-lok™ L Take Apart 10 mm Endoscopic L Clip Applier	544995T	L020802		04/2007
0801902000000 0000000011JV	Weck™ Hem-o-lok™ L Take Apart Endoscopic L Clip Applier, 20 Degree	544995T20	L020802		06/2010
0801902000000 0000000008K8	Weck™ Hem-o-lok™ Open Remover, Straight Jaw, 8” (20 cm)	544122	L21	Tecomet Inc. 5307 95th Ave Kenosha, WI 53144 USA	10/2007
0801902000000 0000000008K8	Weck™ Hem-o-lok™ M, ML, L Open Clip Remover, Straight Jaw, 11” (28 cm)	544123	L21		08/2000
0801902000000 0000000008K8	Weck™ Hem-o-lok™ L, XL Open Clip Remover, Straight Jaw, 11” (28 cm)	544124	L21		11/2001
0801902000000 0000000007K6	Weck™ Hem-o-lok™ ML, L Endoscopic Clip Remover	544121	L21		02/2002
0801902000000 0000000007K6	Weck™ Hem-o-lok™ ML, L Endoscopic Clip Remover	544121L	L21		11/2009
0801902000000 0000000007K6	Weck™ Hem-o-lok™ L, XL Endoscopic Clip Remover	544130	L21		02/2004
0801902000000 0000000007K6	Weck™ Hem-o-lok™ L, XL Endoscopic Clip Remover	544130L	L21		11/2009

Basic UDI-DI	Product Name	Product Code	EMDN/ CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
0801902000000 0000000009KA	Weck™ Hem-o-lok™ ML, L Take Apart 5 mm Endoscopic Clip Remover	544121T	L21	Koscher & Wuertz Einsteinstrasse 7 Spaichingen, DE-BW Germany 78549	04/2007
0801902000000 0000000009KA	Weck™ Hem-o-lok™ L, XL Take Apart 10 mm Endoscopic Clip Remover	544130T	L21		04/2007
0801902000000 0000000009KA	Weck™ Hem-o-lok™ L, XL Take Apart Endoscopic Clip Remover, 20 Degree	544130T20	L21		06/2010
0801902000000 0000000091KM	Weck™ Hem-o-lok™ M Ligating Clip Applier, Curved Jaw, 8” (20 cm), Refurbished	544113R	L020801	Manufacture: Tecomet, Inc. 5307 95th Avenue Kenosha, Wisconsin 53144, USA Refurbishment: Medical Specialties Inc. (MSI) 3874 South Alston Avenue Suite 103 Durham, NC 27713, USA	06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ M Ligating Clip Applier, Right Angled Jaw, 11” (28 cm), Refurbished	544114R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ M Ligating Clip Applier, Curved Jaw, 11” (28 cm), Refurbished	544115R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Curved Jaw, 8” (20 cm), Refurbished	544170R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Curved Jaw, 11” (28 cm), Refurbished	544171R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ ML Ligating Clip Applier, Right Angled Jaw, 11” (28 cm), Refurbished	544172R	L020801		06/2012

Basic UDI-DI	Product Name	Product Code	EMDN/ CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical Inc.
08019020000000000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, 70° Jaw, 11" (28 cm), Refurbished	544179R	L020801		06/2012
08019020000000000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 8" (20 cm), Refurbished	544180R	L020801		06/2012
08019020000000000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 11" (28 cm), Refurbished	544181R	L020801		06/2012
08019020000000000000091KM	Weck™ Hem-o-lok™ L Conduit Ligating Clip Applier, 70° Angle Jaw, 11" (28 cm), Refurbished	544182R	L020801		06/2012
08019020000000000000091KM	Weck™ Hem-o-lok™ XL Ligating Clip Applier, Curved Jaw, 11" (28 cm), Refurbished	544191R	L020801		06/2012
08019020000000000000091KM	Weck™ Hem-o-lok™ XL Ligating Clip Applier, 70° Angled Jaw, 11" (28 cm), Refurbished	544192R	L020801		06/2012
08019020000000000000092KP	Weck™ Hem-o-lok™ S Open Remover, Straight Jaw, 8" (20 cm), Refurbished	544122R	L21	Manufacture: Tecomet, Inc. 5307 95th Avenue Kenosha, Wisconsin 53144, USA Refurbishment: Medical Specialties Inc. (MSI) 3874 South Alston Avenue Suite 103 Durham, NC 27713, USA	06/2012
08019020000000000000092KP	Weck™ Hem-o-lok™ M, ML, L Open Clip Remover, Straight Jaw, 11" (28 cm), Refurbished	544123R	L21		06/2012
08019020000000000000092KP	Weck™ Hem-o-lok™ L, XL Open Clip Remover, Straight Jaw, 11” (28 cm), Refurbished	544124R	L21		06/2012

Approvals

Name and Title of Approver:	Hope West, Principal Regulatory Affairs Specialist – Product Development, Surgical
Signature of Approver:	
Date Approved:	16Jan2023
Place of Issue:	3015 Carrington Mill Blvd Morrisville, NC 27560 USA

Change History for Declaration of Conformity:

Revision	Date	Change Order Number	Reason for Revision
00	See Agile	DCO-057506	Draft release for MDR submission (D039012).
01	See Agile	DCO-067563	Initial release for MDR Compliance (D039012).
02	See Agile	DCO-073902	Updated per D047884, MSI Relocation Project

EC Certificate Full Quality Assurance System: Certificate US19/819943647.00

The management system of

Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 February 2020 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 26 September 2000
and first certified by SGS Belgium NV since 01 February 2020.

Multiple certificates have been issued for this scope.
The main certificate is numbered US19/819943647.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 06866

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

**Sterile Hem-o-lok and Vesolock Ligation Clips,
Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesocclude
Metal Ligation Clips Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II,
"silky" II POLYDEK®, TEVDEK® II, NextStitch®, Capio™, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM
and polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical
Sutures. Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.**

**Sterile and Non-sterile External stapling system (including stainless steel staples,
staplers and removers), Sterile, EFx endo fascial closure system (abdominal access),
Sterile, EFx shield fascial closure system (abdominal access),
Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems, Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades**

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers), Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

375 Forbes Blvd, Mansfield, MA, 02048-1805, United States

EB sertifikato visiško kokybės užtikrinimo sistema: sertifikatas US19/81994367.00

Valdymo sistema

Teleflex Medical

3015 Carrington Mill Blvd.,
Morrisville, NC, 27560, JAV

buvo įvertinta ir sertifikuota kaip atitinkanti

Direktyvos 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsnį) reikalavimus

Šiems produktams

Registracijos sritis pateikiama šio sertifikato 2 puslapyje.
Šis sertifikatas galioja nuo 2020 m. Vasario 24 d. iki 2023 m. Liepos 14 d.
Ir lieka galiojantis atlikus patikimos priežiūros auditą.
2 leidimas. Sertifikuota nuo 2000 m. Rugsėjo 26 d.
ir pirmąjį kartą sertifikuota „SGS Belgium NV“ nuo 2020 m. vasario 1 d.

Šiai sričiai buvo išduoti keli sertifikatai.
Pagrindinis sertifikatas numeruojamas US19/819943647.00

Šis sertifikatą sudaro keli puslapiai
Papildoma informacija pateikiama tolesniuose puslapiuose

Sertifikavimas pagrįstas ataskaitomis, kurių numeris WW/MC 06866

Įgaliojo

parašas

SGS Belgium NV, notifikuotoji įstaiga 1639

SGS House Noorderlaan 87 2030 Antverpenas, Belgija
t el. + 32 (0) 545-48-48 fax. +32 (0) 545-48-49 www.sgs.com

LPMD5007 sertifikatas CE1639 II-4_LT priedas. 02

Teleflex Medical

Direktyva 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsnį) reikalavimus

2 leidimas

Išsami taikymo sritis

Sterilios Hem-o-lok ir Vesolock ligatūrinės kabutės
Sterilios ir nesterilios Hemoclip Traditional, Hemoclip Plus, Horizon ir Vesocclude
metalinės kabutės. Sterilūs Deknatel PTFE lopeliai.
Sterilūs nesirezorbuojantys poliesterio siūlai (POLYLENE/ „cotony“ II, „silky“ II POLYDEK, TEVDEK, NextStich, Capio, NiceLoop, TEVDEK)
Sterilūs DEKLENE II, DEKLENE MAXXTM, CAPIOTM
ir polipropileno nesirezorbuojantys chirurginiai siūlai.
Sterilūs BONDEK ir BONDEK Plus poliglikolinės rūgšties besirezorbuojantys chirurginiai siūlai. Sterilūs Polyglytone 6211 monofilamentiniai besirezorbuojantys chirurginiai siūlai.
Sterilūs MONODEK polydioksanono besirezorbuojantys chirurginiai siūlai.
Sterilūs Hem-o-lok automatinis kabučių aplikatorius.
Metalinė ligavimo sistema.

Sterili ir nesterili išorinė odos susegimo sistema (įskaitant ir nerūdijančio plieno staplerius ir kabučių išėmėjus), Sterili EFx endo fascinio uždarymo sistema (pilvo prieiga),
Sterili EFx viršutinė fascinio uždarymo sistema (pilvo prieiga),
Sterili EFx klasikinė fascinio uždarymo sistema (pilvo prieiga),
Sterilūs plieniniai chirurginiai siūlai
Sterilūs FORCE FIBER chirurginiai siūlai
Sterilios krūtinės drenažo ir autotransfūzinės sistemos, sterilūs troakaro kateteriai
Sterilūs ir nesterilūs aortos skylamušiai
Nesterilus savaime išsilaikantis audinių retractorius, mentės

Sertifikato US19/81994367.00 pratęsimas

Teleflex Medical

Direktyva 93/42/EEB

dėl medicinos prietaisų, II priedas (išskyrus 4 skirsnį) reikalavimus

2 leidimas

Išsami taikymo sritis

Nesterilios anestezijos ir kvėpavimo sistemos, įskaitant kvėpavimo maišelius ir vandens gaudyklės, nesterilūs šildomi drėkintuvai, nesterilūs, neužpildyti Drėkintuvai ir purkštuvai, nesterilūs nedidelio tūrio purkštuvai, Sterilūs užpildyti drėkintuvai ir purkštuvai (fiziologinis tirpalas arba vanduo) su adapteriais,
Sterilus užpildytas vienkartinis dozatorius/tirpalas purškimui,
Nesterilūs kvėpavimo terapijos adapteriai ir jungtys,
Sterili kolona ir rezervuarai, įskaitant adapterius, nesterili nosies kaniulė (Įskaitant dujų mėginių ėmimą), nesterili kaniulė ir maitinimo vamzdeliai, nesterilus CPAP
Kaniulių sistema, nesterilūs rankiniai gaivinimo aparatai ir PEEP vožtuvai,
Nesterilios kvėpavimo ir anestezijos kaukės,
Nesterili dujų šalinimo kaukė, sterilūs endotrachėjos vamzdeliai,
Sterilūs Endobronchiniai vamzdeliai, nesterilūs siurbimo ir aspiravimo vamzdeliai,
Sterilūs ventiliuojami krūtinės ląstos krūtinės įspaudai, sterilūs operaciniai cholanglogramos kateteriai,
Sterilūs pilvo prieigos ir susiurbimo prietaisai,
Sterili kapiliarų drenažo sistema, sterili perkutaninė chirurginė sistema (MiniLap
ir rankenos griebtuvai), sterili perkutaninė chirurginė sistema („Mini Polar“ zondas ir MinlGrip Bipolar Graspers),
Nesterilūs šilumos ir drėgmės keitikliai

Jei pirmiau minėta taikymo sritis apima III klasės medicinos prietaisą (-us), galiojantis EB projekto tyrimo sertifikatas pagal II priedą (4 skirsnį) yra privalomas kiekvieno prietaiso reikalavimas, be šio sertifikato, norint pateikti tą prietaisą į rinką.

Papildomi įrenginiai

375 Forbes Blvd, Mansfield, MA, 02048-1805, JAV

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 540595**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class III		
---	EpiStar CSE - Spinal-Epidural Anaesthesia Kits	See CE 544836
---	Spinostar Spinal Needles	See CE 560441
Class IIb		
10735	Sterile Percutaneous Nephrostomy Catheter	Puncture and dilation of percutaneous approaches into the upper urinary tract.
35404	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients through an existing tracheostoma.
14099	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients, in whom the stoma was created by percutaneous dilative tracheostomy.
58005	Sterile Ureter Stent	Routine drainage of the renal pelvis via the ureter or a ureter-skin stoma to an external collection site.
34924	Sterile Suprapubic Cystotomy Set	Routine suprapubic drainage of the bladder
31074	Sterile Ureterocutaneostomy Catheter	Routine drainage of urine through a ureterocutaneous stoma site.

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Transurethral Catheter	---
MD 0101	Sterile Tracheostomy Retainer Set	---
MD 0106	Sterile Rectal Tube	---
MD 0101 MD 1102	Sterile Breathing Circuit	---
MD 0101 MD 1102	Non-sterile Breathing Circuit	
MD 0101	Sterile Cricothyrotomy Set	---
MD 0102	Sterile Epidural Set	---
MD 0101	Sterile EZ Blocker Kit	---
MD 0106	Sterile Guidewire	---
MD 0106	Sterile Kidney Stone Extractor	---
MD 0101	Sterile Tracheal Tube	---
MD 0101	Non-sterile Tracheal Tube	---
MD 0101	Sterile Laryngeal Mask	---
MD 0101	Non-sterile Laryngeal Mask	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 540595

Issued To:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Sterile Laparoscopy Bag	---
MD 0101	Sterile Bronchial Tube	---
MD 0101	Sterile Suprapubic Cystotomy Set	---
MD 0303	Sterile Drainage Tube	---
MD 0101	Sterile Tracheostomy Tube, Inner cannula	---
MD 0106	Sterile Ureter Catheter	---
MD 0102	Sterile Needle Introducer	---
MD 0101	Sterile Percutaneous Nephrostomy Catheter	---
MD 0106	Non-sterile Temperature Sensor	---
MD 0101	Sterile Breathing Bag	---
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	---

First Issued: **2009-01-13** Date: **2020-06-09** Expiry Date: **2024-05-26**

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	**Design** **Manufacture**
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	**Design**
Arrow Medical Ltd Hatton Garden Industrial Estate Kington Hereford HR5 3RB United Kingdom	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	**Radiation (Gamma Sterilization)**
Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe Seychelles	**Manufacture**
Chemiczna Spółdzielnia Pracy Technochemia ul. Fabryczna 3 05-600 Grójec Poland	**ETO Sterilization**
Contract Medical International, spol. sr.o. Vážní 848 500 03 Hradec Králové Czech Republic	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Daqing Medical Device (Tianjin) Co., Ltd 10A & 11A Tianzhi Industrial Center No.12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin People's Republic of China	**Manufacture**
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	**Manufacture**
Forefront (Xiamen) Medical Devices Co., Ltd No. 28 Haijing East Road & No. 61 Haijing South Road Xiamen Area of China (Fujian) Pilot Free Trade Zone 361026 Xiamen, Fujian People's Republic of China	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Forefront Medical Technology (Pte) Ltd 35 Joo Koon Circle Singapore 629110 Singapore	**Manufacture**
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	**Manufacture**
Medicoplast International GmbH Heusweilerstrasse 100 DE-66557 Illingen Germany	**ETO Sterilization**
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville IN, 46410 United States	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	**Manufacture**
Professional Contract Sterilization Inc. 40 Myles Standish Blvd Taunton Massachusetts 02780-1026 USA	**ETO Sterilization**
safemed medical devices s.r.o Trabantská 292 19015 Praha 9 Czech Republic	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	**ETO Sterilization** **Manufacture**
SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang. Selangor Malaysia	**ETO Sterilization**
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Design** **Manufacture**
SP Medical Sp. z o.o. UI. Ceramiczna 2K 98-220 Zduńska Wola Poland	**Manufacture**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	**ETO Sterilization**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**ETO Sterilization**
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 540595**
Date:	**2020-06-09**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
Teleflex Medical Asia Pte. Ltd. 21 Merchant Road #04-01 Royal Merukh S.E.A 058267 Singapore	**Design** **Manufacture**
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Design** **ETO Sterilization** **Manufacture**
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park Kulim 09000 Malaysia	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture.
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic.
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors.
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture.
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal.
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**
Date: **2020-06-09**
Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S.
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd.
09 March 2015	8293488	Addition of 8 crucial suppliers.
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.
05 August 2016	8571081	Addition of Contract Medical International, spol. sr.o. to the list of significant subcontractors. Addition of EZ Blocker non-active respiratory device.
09 January 2017	8665617	Change to the address of subcontractor (Forefront).
16 July 2018	8939923	Addition of Daqing Medical Device (Tianjin) Co., Ltd to the list of significant subcontractors.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
4 March 2019	7779566	Traceable to NB 0086.
Current	3124666	Certificate renewal. Addition of supplementary product information table. Removal of Control of Sterilization from Service(s) supplied for Arrow International CR, a.s. (Zdar), Arrow International CR, a.s. (Hradec Kralove), Contract Medical International spol. sr.o., SP Medical A/S, sfm medical devices GmbH, Teleflex Medical Asia Pte. Ltd. and Teleflex Medical Sdn. Bhd. Removal of Crucial Supplier from Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd. and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Addition of Manufacture to Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, M.E.M., Inc., Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd., and The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Removal of Manufacture from Service(s) supplied for Arrow International CR, a.s. (Hradec Kralove) Addition of Degania Silicone Limited, safemed medical devices s.r.o and SP Medical Sp. z.o.o. as subcontractors for Manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**

Date: **2020-06-09**

Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Date	Reference Number	Action
		Addition of STERIS AST CZ s.r.o., Synergy Sterilisation (M) Sdn Bhd., Synergy Sterilisation Kulim (M) Sdn Bhd., Chemiczna Spółdzieknia, Medicoplast International GmbH, Professional Contract Sterilization Inc., SINA-SterilGamma Sdn Bhd and Teleflex Medical Sdn. Bhd. as subcontractors for ETO Sterilization. Addition of BBF Sterilisationsservice GmbH as subcontractor for Gamma Sterilization. Removal of CeMed GmbH, Tianjin Medis Medical and Willy Rüsch GmbH Administrative correction of details for Arrow Medical Ltd, Chelle Medical Limited, Contract Medical International spol. sr.o., Daqing Medical Device (Tianjin) Co., Ltd, Forefront (Xiamen) Medical Devices Co., Ltd and SP Medical A/S. Change of address for Teleflex Medical Asia Pte. Ltd. Name change from Süddeutsche Feinmechanik GmbH (SFM) to sfm medical devices GmbH Name change from Parker Medical Systems Division - Merrillville to Parker Hannifin CSS Merrillville

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	UNION MEDICAL SHENZHEN CO.,LTD. ROOM 603, B'UILDING 3, FANTASIA MIC PLAZA, NANHAI AVENUE., NANSHAN DISTRICT, 518062, SHENZHEN, P.R.CHINA
MEDICAL DEVICE INFORMATION:	DISPOSABLE HIGH PRESSURE SYRINGE MODELS SEE ATTACHED LIST A
CLASSIFICATION	ANNEX IX CLASS IIa, RULE 2
UMDNS CODE	13217
MD CODE	MD 0102,MDS 7006-1
CONFORMITY ASSESSMENT ROUTE:	ANNEX II.3
REFER TO REFERENCES STANDARDS:	ISO 7886-1:2017 ISO 8536-4:2019 ISO 80369-7:2016 EN ISO 80369:2017

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

MANUFACTURER ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTRAßE 65 · 80339 MÜNCHEN · GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	G1 094395 0004 REV.00
VALID UNTIL:	2024-05-26
EC REP	
EUROPEAN REPRESENTATIVE:	SHANGHAI INTERNATIONAL HOLDING CORP. GMBH(EUROPE) EIFFESTRAßE 80, 20537, HAMBURG, GERMANY
START OF CE-MARKING:	JULY 7, 2016
PLACE, DATE OF DECLARATION:	SHENZHEN, FEB.19,2021
SIGNATURE:	For and on behalf of Union Medical Shenzhen Co., Ltd. 有限公司 Signature(s) NAME:张文国(ZHANG WENGUO) POSITION: GENERAL MANAGER

List A - Annex to the Declaration of Conformity

Models of Disposable High Pressure Syringe

No.	REF	Contents	Specification
1	SMR101	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
2	SMR102	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
3	SMR103	1-125ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	125ml
4	SMR104	2-200ml Syringes 1-150cm Connector Tube (T tube with one check-valve) 1-long spike for saline 1-short spike for contrast	200/200ml
5	SYW101	1-190ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	190ml
6	SYW102	2-190ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	190/190ml
7	SMR201	1-150ml Syringe 1-Quick Fill Tube	150ml
8	SMR202	1-200ml Syringe 1-Quick Fill Tube	200ml
9	SMR203	1-60ml Syringe 1-Quick Fill Tube	60ml
10	SMR204	1-130ml Syringe 1-Quick Fill Tube	130ml
11	SMR205	1-150ml Syringe 1-Quick Fill Tube	150ml
12	SMR301	2-65ml Syringes 1-250cm Connector Tube (T tube with one check-valve) 1-long spike for saline 1-short spike for contrast	65/65ml

For and on behalf of
Union Medical Shenzhen Co., Ltd.
优尼麦迪克器械(深圳)有限公司

ure(s)

13	SMR302	1-115ml Syringe 1-65ml Syringe 1-250cm Connector Tube (T tube with one check-valve) 1-long spike for saline 1-short spike for contrast	65/115ml
14	SLF101	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
15	SLF102	2-200ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	200/200ml
16	SLF103	1-200ml Syringe 1-150cm Connector Tube (Y tube with two check-valves) 1-Quick Fill Tube 1-Prime Tube	200ml
17	SLF104	1-200ml Syringe 1-150cm Connector Tube (Y tube with one check-valve) 1-Quick Fill Tube 1-Prime Tube	200ml
18	SLF105	1-200ml Syringe 1-long spike 1-Quick Fill Tube	200ml
19	SLF106	1-200ml Syringe	200ml
20	SLF201	1-150ml Syringe 1-Quick Fill Tube	150ml
21	SLF202	1-150ml Syringe 1-Quick Fill Tube	150ml
22	SLF203	1-200ml Syringe 1-Quick Fill Tube	200ml
23	SLF301	2-60ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	60/60ml
24	SNE101	1-100ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-long spike	100ml

For and on behalf of
Union Medical Shenzhen Co., Ltd.
优尼麦迪医疗器械(深圳)有限公司

ature(s)

25	SNE102	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
26	SNE103	1-200ml Syringe 1-60ml Syringe 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	200/60ml
27	SNE104	1-200ml Syringe 1-100ml Syringe 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	200/100ml
28	SNE105	1-200ml Syringe 1-150cm Connector Tube (Y tube with one check-valve) 1-Quick Fill Tube 1-short spike 1-Prime Tube	200ml
29	SNE106	1-100ml Syringe 1- short spike	100ml
30	SNE201	1-120ml Syringe 1-Quick Fill Tube	120ml
31	SNE301	2-60ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	60/60ml
32	SMT101	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
33	SMT102	2-200ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	200/200ml
34	SMT103	1-200ml Syringe	200ml

For and on behalf of
Union Medical Shenzhen Co., Ltd.
优尼麦迪古器械(深圳)有限公司

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35	SMT301	2-65ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	65/65ml
36	SEZ101	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
37	SEZ102	2-200ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast 1-Quick Fill Tube	200/200ml
38	SEZ301	2-100ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	100/100ml
39	SSC101	1-100ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	100ml
40	SSC102	2-100ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 2-Quick Fill Tube	100/100ml
41	SSC103	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml
42	SSC104	2-200ml Syringes 1-150cm Connector Tube (Y tube with one check-valve) 2-Quick Fill Tube	200/200ml
43	SSC201	1-150ml Syringe 1-Quick Fill Tube	150ml
44	SSC202	1-150ml Syringe 1-Quick Fill Tube	150ml
45	SSC301	2-65ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	65/65ml
46	SSC302	1-115ml Syringe 1-65ml Syringe 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	65/115ml

For and on behalf of
Union Medical Shenzhen Co., Ltd.
优尼麦迪医疗器械(深圳)有限公司

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47	SMR105	1-190ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-short spike	190ml
48	SMR106	2-190ml Syringes 1-150cm Connector Tube (T tube with one check-valve) 1-long spike for saline 1-short spike for contrast	190/190ml
49	SMT104	2-200ml Syringes 1-150cm Connector Tube 1-180cm Connector Tube	200/200ml
50	SMT105	2-200ml Syringes 1-150cm Connector Tube 1-180cm Connector Tube 2-Quick fill tubes	200/200ml
51	SMT201	1-200ml Syringe 1-Qucick Fill Tube	200ml
52	SMT202	1-200ml Syringe	200ml
53	SNE107	2-200ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml
54	SNE202	1-150ml Syringe 1-Quick Fill Tube	150ml

For and on behalf of
Union Medical Shenzhen Co., Ltd.
优尼麦迪医疗器械(深圳)有限公司

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ure(s)

ATITIKTIES DEKLARACIJA PAGAL TARYBOS DIREKTYVĄ 93/42/EEB DĖL MEDICINOS PRIETAISŲ

GAMINTOJAS:	UNION MEDICAL SHENZHEN CO.,LTD. ROOM 603, B'JILDING 3, FANTASIA MIC PLAZA, NANHAI AVENUE., NANSHAN DISTRICT, 518062, SHENZHEN, P.R.CHINA
MEDICINOS PRIETAISO INFORMACIJA:	VIENKARTINIS AUKŠTO SLĖGIO ŠVIRKŠTAS MODELIAI ŽR. PRIDĖTŲ **A** SĄRAŠĄ
KLASIFIKACIJA	IX PRIEDAS, IIa KLASĖ, 2 TAISYKLĖ
UMDNS KODAS	13217
MD KODAS	MD 0102,MDS 7006-1
ATITIKTIES ĮVERTINIMO MARŠRUTAS:	11.3 PRIEDAS
ŽR. NUORODŲ STANDARTUS:	ISO 7886-1:2017 ISO 8536-4:2019 ISO 80369-7:2016 EN ISO 80369:2017

MES, GAMINTOJAS, PAREIŠKIAME, KAD NURODYTI MEDICINOS PRIETAISAI ATITINKA PERKĖLIMĄ Į NACIONALINĘ TEISĘ, TARYBOS DIREKTYVOS NUOSTATAS 93/42/EEB DĖL MEDICINOS PRIETAISŲ;

VISI PATVIRTINAMIEJI DOKUMENTAI SAUGOMI GAMINTOJO PATALPOSE.

GAMINTOJAS YRA IŠIMTINAI ATSAKINGAS UŽ DOKUMENTĄ.

NOTIFIKUOTOJI ĮSTAIGA:	TUV SOD PRODUCT SERVICE GMBH RIDLERSTRABE 65 • 80339 MUNCHEN • VOKIETIJA
IDENTIFIKAVIMO NUMERIS	**C E** 0123
(-IAI) SERTIFIKATAS(-AI):	G1 094395 0004 rev.00
GALIOJA IKI:	2024-05-26

EK	REP

ATSTOVAS EUROPOJE: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH(EUROPA)

EIFFESTRAfIE 80, 20537, HAMBURGAS, VOKIETIJA

CE ŽENKLO PRADŽIA: 2016 M. LIEPOS 7 dieną.

/PARAŠAS/

VARDAS, PAVARDĖ: ZHANG WENGUO)

PAREIGOS: GENERALINIS DIREKTORIUS

A sąrašas - Atitikties deklaracijos priedas

Vienkartinio aukšto slėgio švirkšto modeliai

Nr.	REF	Turinys	Parametras
1	SMR101	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1 greito pripildymo vamzdelis	200ml
2	SMR102	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1 greito pripildymo vamzdelis	200ml
3	SMR103	1-125ml švirkštas 1-150 cm jungiamasis vamzdelis - 1 greito pripildymo vamzdelis	125ml
4	SMR104	2-200m1 švirkštai 1-150 cm jungiamasis vamzdelis (T formos vamzdis su vienu atbuliniu vožtuvu) 1 ilgio smaigalys fiziologiniam tirpalui 1 trumpa smaigalė kontrastui	200/200ml
5	SYW101	1-190ml švirkštas 1-150 cm jungiamasis vamzdelis - 1 greito pripildymo vamzdelis	190ml
6	SYW102	2-190ml švirkštai 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1 ilgio smaigalys fiziologiniam tirpalui 1 trumpa smaigalė kontrastui	190/190ml
7	SMR201	1-150ml švirkštas, 1 greito pripildymo vamzdelis	150ml
8	SMR202	1-200ml švirkštas, 1 greito pripildymo vamzdelis	200ml
9	SMR203	1-60ml švirkštas, 1 greito pripildymo vamzdelis	60ml
10	SMR204	1-130ml švirkštas, 1 greito pripildymo vamzdelis	130ml
11	SMR205	1-150ml švirkštas, 1 greito pripildymo vamzdelis	150ml
12	SMR301	2-65ml švirkštas 1-250cm jungiamasis vamzdelis (T vamzdelis su vienu atbuliniu vožtuvu)	65/65ml

13	SMR302	1-115ml švirkštas 1-65ml švirkštas 1-250 cm jungiamasis vamzdelis (T formos vamzdis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	65/115 ml
14	SLF101	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1-greito pripildymo vamzdelis	200ml
15	SLF102	2-200ml švirkštai 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	200/200ml
16	SLF103	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su dviem atbuliniais vožtuvais) 1-greito pripildymo vamzdis 1-Prime Tube	200ml
17	SLF104	1-200m1 švirkštas 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-greito pripildymo vamzdis 1-Prime Tube	200ml
18	SLF105	1-200ml švirkštas 1-ilgio smaigalys 1-greito pripildymo vamzdelis	200ml
19	SLF106	1-200ml švirkštas	200ml
20	SLF201	1-150ml švirkštas, 1-greito pripildymo vamzdelis	150ml
21	SLF202	1-150ml švirkštas, 1-greito pripildymo vamzdelis	150ml
22	SLF203	1-200ml švirkštas, 1-greito pripildymo vamzdelis	200ml
23	SLF301	2-60m1 švirkštai 1-250 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1 ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	60/60ml

24	SNE101	1-100ml švirkštas 1-150 cm jungiamasis vamzdelis 1-Greito pripildymo vamzdis,	100ml
25	SNE102	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1 greito pripildymo vamzdelis	200ml
26	SNE103	1-200ml švirkštas 1-60ml švirkštas 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1 ilgio smaigalys fiziologiniam tirpalui 1 trumpa smaigalė kontrastui	200/60ml
27	SNE104	1-200ml švirkštas 1-100ml švirkštas 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	200/100ml
28	SNE105	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-greito pripildymo vamzdis 1-trumpa smaigalė	200ml
29	SNE106	1-100ml švirkštas 1- trumpas smaigas	100ml
30	SNE201	1-120ml švirkštas, 1-greito pripildymo vamzdelis	120ml
31	SNE301	2-60ml švirkštai 1-250 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui	60/60ml
32	SMT101	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis 1-greito pripildymo vamzdelis	200ml
33	SMT102	2-200ml švirkštai 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui	200/200ml
34	SMT103	1-200ml švirkštas	200ml

35	SMT301	2-65ml švirkštai 1-250 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui	65/65ml
36	SEZ101	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1-greito pripildymo vamzdelis	200ml
37	SEZ102	2-200ml švirkštai 1-150 cm jungties vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpas smaigalys kontrastui 1-greito pripildymo vamzdelis	200/200ml
38	SEZ301	2-100ml švirkštai 1-250 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	100/100ml
39	SSC101	1-100ml švirkštas 1-150 cm jungiamasis vamzdelis 1-greito pripildymo vamzdelis	100ml
40	SSC102	2-100 ml švirkštai 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu)	100/100ml
41	SSC103	1-200ml švirkštas 1-150 cm jungiamasis vamzdelis - 1-greito pripildymo vamzdelis	200ml
42	SSC104	2-200ml švirkštai 1-150 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 2-greitojo pildymo vamzdis	200/200ml
43	SSC201	1-150ml švirkštas, 1-greito pripildymo vamzdelis	150ml
44	SSC202	1-150ml švirkštas, 1-greito pripildymo vamzdelis	150ml
45	SSC301	2-65ml švirkštai 1-250 cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui	65/65ml

46	SSC302	1-115ml švirkštas 1-65ml švirkštas 1-250cm jungiamasis vamzdelis (Y formos vamzdelis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	65/115ml
47	SMR105	1-190ml švirkštas 1-150 cm jungties vamzdelis 1-greito pripildymo vamzdis 1-trumpas smaigalys	190ml
48	SMR106	2-190ml švirkštai 1-150 cm jungiamasis vamzdelis (T formos vamzdis su vienu atbuliniu vožtuvu) 1-ilgio smaigalys fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	190/190ml
49	SMT104	2-200ml švirkštai 1-150 cm jungiamasis vamzdelis 1-180 cm jungiamasis vamzdelis	200/200ml
50	SMT105	2-200ml švirkštai 1-150 cm jungties vamzdelis 1-180 cm jungiamasis vamzdelis, 2-greito pripildymo vamzdeliai	200/200ml
51	SMT201	1-200ml švirkštas 1-Quucick pripildymo vamzdelis	200ml
52	SMT202	1-200ml švirkštas	200ml
53	SNE107	2-200ml švirkštas 1-250 cm 1- ilgio jungties vamzdelis fiziologiniam tirpalui 1-trumpa smaigalė kontrastui	200/200ml

54	SNE202	1-150m1 švirkštas, 1-greito pripildymo vamzdelis	150ml

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2024-05-24

Our reference: QS-20383

Notified Body Confirmation Letter
Certification No: 20383GB454240524

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

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], 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.

Union Medical Shenzhen Co., Ltd.
Room 603, Building 3, Fantasia MIC Plaza, Nanhai Avenue,
Nanshan District, 518062, Shenzhen,
China
SRN[2]: CN-MF-000012410

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a 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 20 March 2023 for the relevant devices.

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

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 devices, 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)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

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

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
SYRINGES FOR CONTRAST MEDIA INJECTOR, SINGLE-USE	**Class IIa**	**N/A**	**G10943950004REV.00 NB 0123**
NEEDLE CONNECTORS AND ADAPTERS	**Class IIa**	**N/A**	**G10943950004REV.00 NB 0123**

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-05-24	20383GB454240524	Initial issue

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

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

Product Service

EC Certificate

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

No. G1 094395 0004 Rev. 00

Manufacturer: **Union Medical Shenzhen Co.,Ltd.**
Room 603, Building 3
Fantasia MIC Plaza, Nanhai Avenue
Nanshan District
518062 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Disposable High Pressure Syringe and Disposable Pressure Connector Tube**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 094395 0004 Rev. 00

Report No.: GZ2024503

Valid from: 2021-02-02
Valid until: 2024-05-26

Date, 2021-02-02

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV®

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

ZLG-BS-244.10.08

Product Service

CE Sertifikatas

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

No. G1 094395 0004 Perž. 00

Gamintojas:

Union Medical Shenzhen Co., Ltd.
Room 603, Building 3
Fantasia MIC Plaza,
Nanhai Avenue
Nanshan Dsitrict
518062 Shenzhen
Kinija

Produkto kategorija (-os):

Vienkartinis aukšto spaudimo švirkštas ir vienkartinė prailginimo linija

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

Ataskaita Nr.: GZ2024503

Galioja nuo: 2021-02-02
Galioja iki: 2024-05-26

Data, 2021-02-02

Christoph Dicks
Notifikuotosios įstaigos vadovas

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

TUV SUD Product Service GmbH • Notifikuotoji įstaiga • Ridler g. 65 • 80339 Miunchenas • Vokietija

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

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Manufacturer:

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

SRN Manufacturer - CN-MF-000006728

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 038814 0092 Rev. 01

Report No.: SH2308001

Preceding Certificate No.: G10 038814 0092 Rev. 00

Valid from: 2023-12-12
Valid until: 2028-05-15
Date of Initial Issuance: 2023-05-16

Issue date: 2023-12-12

Christoph Dicks
Head of Certification/Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Classification:	Class IIa
Device Group:	A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Intended Purpose:	/
Classification:	Class IIa
Device Group:	A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010101 - NASOPHARYNGEAL TUBES
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010201 - LARYNGEAL MASKS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010301 - ENDOTRACHEAL TUBES, CUFFLESS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010302 - ENDOTRACHEAL TUBES, CUFFED
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010380 - ENDOTRACHEAL TUBES - ACCESSORIES
Intended Purpose:	/

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BS-MDR-099

TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Classification:	Class IIa
Device Group:	R010401 - ENDOBRONCHIAL TUBES, RIGHT
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010402 - ENDOBRONCHIAL TUBES, LEFT
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R010499 - ENDOBRONCHIAL TUBES - OTHER
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R020107 - THERMOREGULATED BREATHING CIRCUITS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R020299 - MOUNT CATHETERS - OTHER
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R028099 - RESPIRATORY CIRCUITS AND MOUNT CATHETERS - ACCESSORIES NOT INCLUDED IN OTHER CLASSES
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R030101 - VENTILATION MASKS
Intended Purpose:	/

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Classification:	Class IIa
Device Group:	R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U010105 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U020301 - SINGLE LOOP URETERAL STENTS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U030101 - SEQUENTIAL DILATORS FOR PERCUTANEOUS NEPHROSTOMY
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U030102 - URETHRAL AND URETERAL DILATORS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U030202 - URETERAL DILATORS, WITH BALLOON
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U040101 - KITS WITH DRAINAGE CATHETERS, DIRECT PUNCTURE
Intended Purpose:	/

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Classification:	Class IIa
Device Group:	U040102 - KITS WITH DRAINAGE CATHETERS AND INTRODUCERS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U040199 - DEVICES FOR SUPRAPUBIC URINARY DRAINAGE - OTHER
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U050301 - URETHRAL PRESSURE PROFILE CATHETERS WITHOUT BALLOON
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U0599 - URODYNAMICS DEVICES - OTHER
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC
Intended Purpose:	/
Classification:	Class IIa
Device Group:	U090101 - URINARY STONE RETRIEVAL BASKETS
Intended Purpose:	/
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 038814 0092 Rev. 01

Revision History:

Rev.	Dated	Report	Description
00	2023-05-16	SH21080MDR01	Initial issuance
01	2023-12-12	SH2308001	Supplemented: Device(s)/group of device(s) added

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Document Nr.: WL-DOC-002/A

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Repre-sentative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestraβe 80, 20537 Hamburg, GERMANY
Product Name:	Tracheal Tube
Size:	Refer to Annex
UMDNS Code:	14085

Classification (MDD, Annex IX): **IIa, Rule 5**

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

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

DIRECTIVES

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

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	**G1 038814 0086 Rev. 01**
Expire date of the Certificate:	**2024-05-26**
Start of CE Marking:	**2003**
Place, Date of Issue:	**Guangzhou, 2021-02-20**

Signature: _

Name: Chen Yun Gui

Position: **Management Representative**

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

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

Document Nr.:WL-DOC-002A

Annex

Variants of Tracheal Tube

Model	Size, I.D(mm)			
	Type			
	HVLP* cuffed	LP* cuffed	PU cuffed	Uncuffed
Standard Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0, 10.5, 11.0	2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0,	2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0, 10.5, 11.0
Oral Tra-cheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0
Nasal Tracheal Tube	3.0, 3.5,4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0
Oral North	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	/	/	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0
Softline Nasal Pre-formed	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	/	/	2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Microlar-yngeal ET Tube	4.0, 5.0, 6.0	/	/	/

Parker Series

Model	Size, I.D(mm)			
	Type			
	HVLP* cuffed	LP* cuffed	PU cuffed	Uncuffed
Standard Tra-cheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0,	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0,	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0
Oral Tracheal Tube	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0
Nasal Trache-al Tube	3.0, 3.5,4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0	3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5,10.0
Microlaryngeal ET Tube	4.0, 5.0, 6.0			/

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

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Document Nr.: WL-DOC-003/B

Declaration of Conformity

Manufacturer:	**Well Lead Medical Co., Ltd.** C-4 Jinhu Industrial Estate, Hualong 511434 Panyu, Guangzhou, People Republic of China
European Repre-sentative:	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestraβe 80, 20537 Hamburg, GERMANY
Product Name:	Tracheostomy Tube
Model or Size:	Model: Tracheostomy Tube Type: Type I Size: ID 3.0, ID 3.5, ID 4.0, ID 4.5, ID 5.0, ID 5.5, ID 6.0, ID 6.5, ID 7.0, ID 7.5, ID 8.0, ID 8.5, ID 9.0, ID 9.5, ID 10.0 Type: Type II Size: ID 3.0, ID 3.5, ID 4.0, ID 4.5, ID 5.0, ID 5.5, ID 6.0, ID 6.5, ID 7.0, ID 7.5, ID 8.0, ID 8.5, ID 9.0, ID 9.5, ID 10.0 Model: Suction Plus Size: I.D 6.0, I.D 6.5, I.D 7.0, I.D 7.5, I.D 8.0, I.D 8.5, I.D 9.0 (incl. PVC(DEHP) and PVC(DEHP-Free))
GMDN Code:	35404

Classification (MDD, Annex IX): **IIb, Rule 5**

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

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

DIRECTIVES

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

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany
Identification number:	CE0123
(EC) Certificate(s):	**G1 038814 0079 Rev. 00**
Expire date of the Certificate:	**2024-05-26**
Start of CE Marking:	**2003**
Place, Date of Issue:	**Guangzhou, 2021-02-20**

Signature: —

Name: Chen Yun Gui

Position: **Management Representative**

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

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

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)

Manufacturer name	ZARYS International Group sp. z o.o. sp.k.
Manufacturer address and contact details	ul. Pod Borem 18, 41-808 Zabrze, Poland
Single Registration Number (SRN)	PL-MF-000000410

Notified body name and address	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany
Notified body number	0197
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met

namely by fulfilling the following conditions:

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

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

✓ Expired/expires *after* 20 March 2023:

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

- **Quality Management System (QMS)**
  - ✓ A QMS in accordance with Article 10(9) MDR is in place.

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

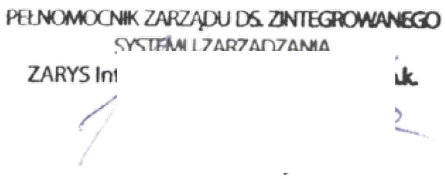
Signed for and on behalf of the manufacturer:

Full Company Name: ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa

Location & Date: Zabrze, 1.03.2024

Name, Title: Joanna Skiba-Klyta, Quality and Regulatory Affairs Department Coordinator/ Management Board's Representative for Integrated Management Systems

Contact Details: qm@zarys.pl



Schedule of Devices

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

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Device Classification**	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**End date of extended validity / transition period**
Sterile and non-sterile cutting gauze	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Non-sterile dressing gauze	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze swabs (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze balls (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze rolls (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile non-woven swabs (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile paraffin gauze dressings	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile three-way stopcocks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile transfusion sets for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile infusion sets for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile extension tubes for infusion pump	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile endotracheal tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile tracheostomy tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile breathing circuits	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile catheter mounts	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Non-sterile anaesthetic masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile laryngeal masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile oxygen masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile Venturi masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile non-rebreath masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nebulizer masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nasal oxygen cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nebulizers	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile oxygen tubing	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile suction catheters	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile feeding tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile stomach and duodenal tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile urology catheters	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical suction sets	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical suction cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028

Sterile syringes for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile insulin syringes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile tuberculin syringes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile hypodermic needles	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile insulin pen needles	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile blood lancets	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile IV cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile needle free valves	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical gloves	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile procedure kits	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Elastic bandages	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Adhesive cannula fixation dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Adhesive wound dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Eye pads	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Incise films	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Transparent film dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Absorbent wound dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Surgical gowns	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Surgical drapes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Sets of surgical drapes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Fluid collection pouches	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Nelaton catheters	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Vaginal speculums	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Cervical brushes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Urine bags	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Enema bags	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Tongue depressors	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Oropharyngeal airways	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Intubation stylets	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Endotracheal tube holders	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Suction tubes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Withdrawal cannulas	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Cannula stoppers	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Umbilical cord clamps	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical sets	Class IIa	HD 1023663-1	26 May 2024	31 December 2028
Sterile procedure kits	Class IIa	HD 1023663-1	26 May 2024	31 December 2028
Sterile surgical sets	Class IIb	HD 1023663-1	26 May 2024	31 December 2028
Surgical gowns	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Surgical drapes	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Sets of surgical drapes	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Procedure kits	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Knitted bandages	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa
ul. Pod Borem 18,
41-808 Zabrze,
Poland

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 15, 2024

Notified Body Confirmation Letter
Reference. : ZARYS_PLA0_HZ_2024-05-10/ 84965323

To whom it may concern,

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

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa
ul. Pod Borem 18,
41-808 Zabrze,
Poland
SRN Number: PL-MF-000000410

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 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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)

ɔtified Body

ata Blazniak
15 13:38:01

Certification body

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
GAZA lux S **Cutting gauze, sterile** **Basic UDI-DI:** **59079968M02010101-ERR**	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
GAZA lux S **Cutting gauze, sterile** **Basic UDI-DI:** **59079968M02010101-SSM**	Class IIa	GAZA lux S Cutting gauze, sterile	DD 1023663-1 NB 0197
GAZA lux **Cutting gauze, non-sterile** **Basic UDI-DI:** **59079968M02010101-NSB**	Class IIa	GAZA lux Cutting gauze, non-sterile	DD 1023663-1 NB 0197
GAZA lux **Dressing gauze, non-sterile** **Basic UDI-DI:** **59079968M020107DG**	Class IIa	GAZA lux Dressing gauze, non-sterile	DD 1023663-1 NB 0197
KOMPRI lux S	Class IIa	KOMPRI lux S	DD 1023663-1 NB 0197

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**
Gauze swabs without X-ray thread, sterile **Basic UDI-DI: 59079968M02010201-ES4**		Gauze swabs without X-ray thread, sterile	
KOMPRI lux S **Gauze swabs without X-ray thread, sterile** **Basic UDI-DI: 59079968M02010201-SSY**	Class IIa	KOMPRI lux S Gauze swabs without X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S **Gauze swabs with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010202-ES9**	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux S **Gauze swabs with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010202-ST5**	Class IIa	KOMPRI lux S Gauze swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
KOMPRI lux **Gauze swabs without X-ray thread, non-sterile** **Basic UDI-DI: 59079968M02010201-NSN**	Class IIa	KOMPRI lux Gauze swabs without X-ray thread, non-sterile	DD 1023663-1 NB 0197
KOMPRI lux **Gauze swabs with X-ray thread, non-sterile** **Basic UDI-DI: 59079968M02010202-NST**	Class IIa	KOMPRI lux Gauze swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SERVI lux S **Gauze lap sponges with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010302-ESL**	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S **Gauze lap sponges with X-ray thread, sterile** **Basic UDI-DI: 59079968M02010302-STG**	Class IIa	SERVI lux S Gauze lap sponges with X-ray thread, sterile	DD 1023663-1 NB 0197
SERVI lux S **Gauze lap sponges with X-ray chip, pre-washed, sterile**	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968M02010302-PE86			
SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile **Basic UDI-DI: 59079968M02010302-PS92**	Class IIa	SERVI lux S Gauze lap sponges with X-ray chip, pre-washed, sterile	DD 1023663-1 NB 0197
SERVI lux Gauze lap sponges with X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010302-NT6**	Class IIa	SERVI lux Gauze lap sponges with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile **Basic UDI-DI: 59079968M02010302-PN8Q**	Class IIa	SERVI lux Gauze lap sponges with X-ray chip, pre-washed, non-sterile	DD 1023663-1 NB 0197
TUPFER lux S Gauze balls without X-ray thread, sterile **Basic UDI-DI: 59079968M02010501-ET5**	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S Gauze balls without X-ray thread, sterile **Basic UDI-DI: 59079968M02010501-STZ**	Class IIa	TUPFER lux S Gauze balls without X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S Gauze balls with X-ray thread, sterile **Basic UDI-DI: 59079968M02010502-ETA**	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux S Gauze balls with X-ray thread, sterile **Basic UDI-DI: 59079968M02010502-SU6**	Class IIa	TUPFER lux S Gauze balls with X-ray thread, sterile	DD 1023663-1 NB 0197
TUPFER lux Gauze balls without X-ray thread, non-sterile	Class IIa	TUPFER lux Gauze balls without X-ray thread, non-sterile	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968M02010501-NTP			
TUPFER lux Gauze balls with X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010502-NTU**	Class IIa	TUPFER lux Gauze balls with X-ray thread, non-sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls without X-ray thread, sterile **Basic UDI-DI: 59079968M02010701-SUP**	Class IIa	SETON lux S Gauze rolls without X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls with X-ray thread, sterile **Basic UDI-DI: 59079968M02010702-ETY**	Class IIa	SETON lux S Gauze rolls with X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux S Gauze rolls with X-ray thread, sterile **Basic UDI-DI: 59079968M02010702-SUU**	Class IIa	SETON lux S Gauze rolls with X-ray thread, sterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls without X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010701-NUD**	Class IIa	SETON lux Gauze rolls without X-ray thread, non-sterile	DD 1023663-1 NB 0197
SETON lux Gauze rolls with X-ray thread, non-sterile **Basic UDI-DI: 59079968M02010702-NUJ**	Class IIa	SETON lux Gauze rolls with X-ray thread, non-sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile **Basic UDI-DI: 59079968M02020101-ESA**	Class IIa	NONVI lux S Non-woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swab, sterile **Basic UDI-DI: 59079968M02020101-ST6**	Class IIa	NONVI lux S Non-woven swabs, sterile	DD 1023663-1 NB 0197
NONVI lux S Non-woven swabs with X-ray thread, sterile	Class IIa	NONVI lux S Non-woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968M02020102-ESF			
NONVI lux S **Non-woven swabs with X-ray thread, sterile** **Basic UDI-DI: 59079968M02020102-STB**	Class IIa	NONVI lux S Non-woven swabs with X-ray thread, sterile	DD 1023663-1 NB 0197
NONVI lux **Non-woven swabs, non-sterile** **Basic UDI-DI: 59079968M02020101-NSU**	Class IIa	NONVI lux Non-woven swabs, non-sterile	DD 1023663-1 NB 0197
NONVI lux **Non-woven swabs with X-ray thread, non-sterile** **Basic UDI-DI: 59079968M02020102-NSZ**	Class IIa	NONVI lux Non-woven swabs with X-ray thread, non-sterile	DD 1023663-1 NB 0197
paraffiNET **Paraffin gauze dressing, sterile** **Basic UDI-DI: 59079968M020302DG**	Class IIa	paraffiNET Paraffin gauze dressing, sterile	DD 1023663-1 NB 0197
SANVIflon I.V. cannula **SANVIflon S I.V. cannula without injection port** **SANVIflon premium I.V. cannula** **SANVIflon safe Safety I.V. cannula** **Basic UDI-DI: 59079968C0101017F**	Class IIa	SANVIflon I.V. cannula SANVIflon S I.V. cannula without injection port SANVIflon premium I.V. cannula SANVIflon safe Safety I.V. cannula	DD 1023663-1 NB 0197
OXYGEN TUBING **Basic UDI-DI: 59079968R03010204LA**	Class IIa	OXYGEN TUBING	DD 1023663-1 NB 0197
NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing **Basic UDI-DI: 59079968R030103-FMV5**	Class IIa	NEBULIZER with T F/M adaptor, mouthpiece, corrugated tube and tubing	DD 1023663-1 NB 0197
NEBULIZER mask with tubing **Basic UDI-DI: 59079968R030103-MMN**	Class IIa	NEBULIZER with mask and tubing	DD 1023663-1 NB 0197

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**
OXYGEN MASK with tubing **Basic UDI-DI: 59079968R03010201L4**	Class IIa	OXYGEN MASK with tubing	DD 1023663-1 NB 0197
NON-REBREATHER MASK with tubing **Basic UDI-DI: 59079968R03010206LE**	Class IIa	NON-REBREATHER MASK with tubing	DD 1023663-1 NB 0197
VENTURI MASK with adjustable diluter and tubing **Basic UDI-DI: 59079968R03010202-AXK**	Class IIa	VENTURI MASK with adjustable diluter and tubing	DD 1023663-1 NB 0197
NASAL OXYGEN CANNULA for adults **NASAL OXYGEN CANNULA for children** **NASAL OXYGEN CANNULA for infants** **Basic UDI-DI: 59079968R03010203L8**	Class IIa	NASAL OXYGEN CANNULA for adults NASAL OXYGEN CANNULA for children NASAL OXYGEN CANNULA for infants	DD 1023663-1 NB 0197
SUCTION CATHETER **SUCTION CATHETER IDEAL** **SUCTION CATHETER with vacuum control** **SUCTION CATHETER with vacuum control IDEAL** **Basic UDI-DI: 59079968R0501QP**	Class IIa	SUCTION CATHETER SUCTION CATHETER IDEAL SUCTION CATHETER with vacuum control SUCTION CATHETER with vacuum control IDEAL	DD 1023663-1 NB 0197
Two-way Foley catheter with rubber valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-LRXH**	Class IIa	TWO-WAY FOLEY CATHETER with rubber valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-LPXD**	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve (100% silicone, X-ray contrast)	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968U010201-SP6			
Three-way Foley catheter with plastic valve (silicone-coated latex) **Basic UDI-DI: 59079968U010201-3LUV**	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Three-way Foley catheter with plastic valve (100% silicone, X-ray contrast) **Basic UDI-DI: 59079968U010201-3SVB**	Class IIa	THREE-WAY FOLEY CATHETER with plastic valve	DD 1023663-1 NB 0197
Two-way Foley catheter with plastic valve, Tiemann tip (silicone-coated latex) **Basic UDI-DI: 59079968U0102R6**	Class IIa	TWO-WAY FOLEY CATHETER with plastic valve, Tiemann tip	DD 1023663-1 NB 0197
TIEMANN CATHETER **Basic UDI-DI: 59079968U010106HB**	Class IIa	TIEMANN CATHETER	DD 1023663-1 NB 0197
PEZZER CATHETER **Basic UDI-DI: 59079968U010107HD**	Class IIa	PEZZER CATHETER	DD 1023663-1 NB 0197
FEEDING TUBE **Basic UDI-DI: 59079968G02020101BU**	Class IIa	FEEDING TUBE	DD 1023663-1 NB 0197
STOMACH TUBE DUODENAL TUBE **Basic UDI-DI: 59079968G020201A3**	Class IIa	STOMACH TUBE DUODENAL TUBE	DD 1023663-1 NB 0197
SUCTION CANNULA with suction control SUCTION CANNULA without suction control **Basic UDI-DI: 59079968A06010184**	Class IIa	SUCTION CANNULA with suction control SUCTION CANNULA without suction control	DD 1023663-1 NB 0197
SUCTION CANNULA with suction control, ball tip SUCTION CANNULA without suction control, ball tip **Basic UDI-DI: 59079968A060101-BA2**	Class IIa	SUCTION CANNULA with suction control, ball tip SUCTION CANNULA without suction control, ball tip	DD 1023663-1 NB 0197

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**
SURGICAL SUCTION SET with suction control, Yankauer tip **SURGICAL SUCTION SET without suction control, Yankauer tip** **Basic UDI-DI: 59079968A060101039F**	Class IIa	SURGICAL SUCTION SET with suction control, Yankauer tip SURGICAL SUCTION SET without suction control, Yankauer tip	DD 1023663-1 NB 0197
SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, Yankauer tip **SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, Yankauer tip** **Basic UDI-DI: 59079968A06010103-FFUC**	Class IIa	SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, Yankauer tip SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, Yankauer tip	DD 1023663-1 NB 0197
SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip **SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip** **Basic UDI-DI: 59079968A06010103-FFB6J**	Class IIa	SURGICAL SUCTION SET with suction control, funnel-funnel cut-to-fit, ball tip SURGICAL SUCTION SET without suction control, funnel-funnel cut-to-fit, ball tip	DD 1023663-1 NB 0197
SUCTION TUBE funnel-funnel **Basic UDI-DI: 59079968A060304-FFG4**	Class IIa	SUCTION TUBE funnel-funnel	DD 1023663-1 NB 0197
SUCTION TUBE funnel-funnel cut-to-fit **Basic UDI-DI: 59079968A060304-FCFW**	Class IIa	SUCTION TUBE funnel-funnel cut-to-fit	DD 1023663-1 NB 0197
SUCTION TUBE funnel-Kapkon **Basic UDI-DI: 59079968A060304-FKGE**	Class IIa	SUCTION TUBE funnel-Kapkon	DD 1023663-1 NB 0197
easyWAY Three-way stopcock	Class IIa	easyWAY Three-way stopcock	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968A0703KA			
easyWAY L Three-way stopcock with extension **Basic UDI-DI: 59079968A0703-LA4**	Class IIa	easyWAY L Three-way stopcock with extension	DD 1023663-1 NB 0197
easyFLOW LINE Extension tube for infusion pump, phthalate-free **Basic UDI-DI: 59079968A03020178**	Class IIa	easyFLOW LINE Extension tube for infusion pump, phthalate-free	DD 1023663-1 NB 0197
easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free **Basic UDI-DI: 59079968A030201-A8Q**	Class IIa	easyFLOW LINE AMBER Extension tube for infusion pump, amber, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS Infusion set easyFLOW IS ECO Infusion set **Basic UDI-DI: 59079968A03010103-PHT6H**	Class IIa	easyFLOW IS Infusion set easyFLOW IS ECO Infusion set	DD 1023663-1 NB 0197
easyFLOW IS Infusion set, phthalate-free easyFLOW IS ECO Infusion set, phthalate-free easyFLOW IS PREMIUM Infusion set, phthalate-free **Basic UDI-DI: 59079968A030101037U**	Class IIa	easyFLOW IS Infusion set, phthalate-free easyFLOW IS ECO Infusion set, phthalate-free easyFLOW IS PREMIUM Infusion set, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS SAFE Safety infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free **Basic UDI-DI: 59079968A03010103-SG2**	Class IIa	easyFLOW IS SAFE Safety infusion set, phthalate-free easyFLOW IS SAFE PREMIUM Safety infusion set, phthalate-free	DD 1023663-1 NB 0197
easyFLOW IS REG Infusion set with precision flow rate regulator, phthalate-free	Class IIa	easyFLOW IS REG Infusion set with precision flow rate	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968A03010103-RFY		regulator, phthalate-free	
easyFLOW IS AMBER Infusion set, amber, phthalate-free **Basic UDI-DI: 59079968A03010103-AEW**	Class IIa	easyFLOW IS AMBER Infusion set, amber, phthalate-free	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE UNCUFFED **Basic UDI-DI: 59079968R010301FQ**	Class IIa	ENDOTRACHEAL TUBE UNCUFFED	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE CUFFED **Basic UDI-DI: 59079968R010302FS**	Class IIa	ENDOTRACHEAL TUBE CUFFED	DD 1023663-1 NB 0197
REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET **Basic UDI-DI: 59079968R010302-RMF**	Class IIa	REINFORCED ENDOTRACHEAL TUBE CUFFED WITH PRELOADED STYLET	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm **BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm** **Basic UDI-DI: 59079968R0201-BGG**	Class IIa	BREATHING CIRCUIT FOR CHILDREN with bag, expandable, additional arm BREATHING CIRCUIT FOR ADULTS with bag, expandable, additional arm	DD 1023663-1 NB 0197
BREATHING CIRCUIT FOR CHILDREN **BREATHING CIRCUIT FOR ADULTS** **Basic UDI-DI: 59079968R0201Q8**	Class IIa	BREATHING CIRCUIT FOR CHILDREN BREATHING CIRCUIT FOR ADULTS	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, smooth-bore **Basic UDI-DI: 59079968R020202-SMP**	Class IIa	CATHETER MOUNT with double swivel elbow connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with double swivel elbow connector, expandable	Class IIa	CATHETER MOUNT with double swivel	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968R020202-ELT		elbow connector, expandable	
CATHETER MOUNT with double swivel elbow connector, corrugated **Basic UDI-DI: 59079968R020202-CLP**	Class IIa	CATHETER MOUNT with double swivel elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, smooth-bore **Basic UDI-DI: 59079968R020201-SMJ**	Class IIa	CATHETER MOUNT with straight connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, corrugated **Basic UDI-DI: 59079968R020201-CLJ**	Class IIa	CATHETER MOUNT with straight connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with straight connector, expandable **Basic UDI-DI: 59079968R020201-ELN**	Class IIa	CATHETER MOUNT with straight connector, expandable	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, smooth-bore **Basic UDI-DI: 59079968R0202-SHP**	Class IIa	CATHETER MOUNT with elbow connector, smooth-bore	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, corrugated **Basic UDI-DI: 59079968R0202-CGP**	Class IIa	CATHETER MOUNT with elbow connector, corrugated	DD 1023663-1 NB 0197
CATHETER MOUNT with elbow connector, expandable **Basic UDI-DI: 59079968R0202-EGT**	Class IIa	CATHETER MOUNT with elbow connector, expandable	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE cuffed **Basic UDI-DI: 59079968R010502G4**	Class IIa	TRACHEOSTOMY TUBE cuffed	DD 1023663-1 NB 0197
TRACHEOSTOMY TUBE uncuffed	Class IIa	TRACHEOSTOMY TUBE uncuffed	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968R010501G2			
LARYNGEAL MASK, PVC, disposable **Basic UDI-DI: 59079968R0102-PH6**	Class IIa	LARYNGEAL MASK, PVC, disposable	DD 1023663-1 NB 0197
LARYNGEAL MASK, silicone, disposable **Basic UDI-DI: 59079968R0102-SHC**	Class IIa	LARYNGEAL MASK, silicone, disposable	DD 1023663-1 NB 0197
AIR CUSHION ANAESTHETIC MASK **Basic UDI-DI: 59079968R030101-CLQ**	Class IIa	AIR CUSHION ANAESTHETIC MASK	DD 1023663-1 NB 0197
ANAESTHETIC MASK with open seal **Basic UDI-DI: 59079968R030101-OMG**	Class IIa	ANAESTHETIC MASK with open seal	DD 1023663-1 NB 0197
duoNEX **Single use syringe, 2-part** **Basic UDI-DI: 59079968A0201020101DK**	Class IIa	duoNEX Single use syringe, 2-part	DD 1023663-1 NB 0197
dicoNEX **Single use syringe, 3-part (luer)** **Basic UDI-DI: 59079968A0201020102DM**	Class IIa	dicoNEX Single use syringe, 3-part (luer)	DD 1023663-1 NB 0197
Apteczka ABC **Strzykawka 3-częściowa** **Basic UDI-DI: 59079968A0201020102DM**	Class IIa	Apteczka ABC Strzykawka 3-częściowa	DD 1023663-1 NB 0197
dicoNEX **Single use syringe, 3-part (luer lock)** **Basic UDI-DI: 59079968A0201020201DQ**	Class IIa	dicoNEX Single use syringe, 3-part (luer lock)	DD 1023663-1 NB 0197
dicoNEX **Single use amber syringe, 3-part (luer lock)** **Basic UDI-DI: 59079968A0201020201-AVY**	Class IIa	dicoNEX Single use amber syringe, 3-part (luer lock)	DD 1023663-1 NB 0197
dicoNEX	Class IIa	dicoNEX	DD 1023663-1 NB 0197

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**
Single use catheter syringe, 3-part **Basic UDI-DI: 59079968A020102037G**		Single use catheter syringe, 3-part	
dicoNEX MN Single use syringe, 3-piece with mounted needle (luer) **dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer)** **Basic UDI-DI: 59079968A0201020102-IWA**	Class IIa	dicoNEX MN Single use syringe, 3-piece with mounted needle (luer) dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer)	DD 1023663-1 NB 0197
dicoNEX MN Single use syringe, 3-piece with mounted needle (luer lock) **dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer lock)** **Basic UDI-DI: 59079968A0201020201-IWG**	Class IIa	dicoNEX MN Single use syringe, 3-piece with mounted needle (luer lock) dicoNEX SN Single use syringe, 3-piece, with needle alongside the syringe (luer lock)	DD 1023663-1 NB 0197
dicoNEX MN Single use amber syringe, 3-piece with mounted needle (luer lock) **dicoNEX SN Single use amber syringe, 3-piece, with needle alongside the syringe (luer lock)** **Basic UDI-DI: 59079968A0201020201-IA9D**	Class IIa	dicoNEX MN Single use amber syringe, 3-piece with mounted needle (luer lock) dicoNEX SN Single use amber syringe, 3-piece, with needle alongside the syringe (luer lock)	DD 1023663-1 NB 0197
dicoSULIN Insulin syringe **Basic UDI-DI: 59079968A02010672**	Class IIa	dicoSULIN Insulin syringe	DD 1023663-1 NB 0197
dicoTUBER Tuberculin syringe **Basic UDI-DI: 59079968A02010978**	Class IIa	dicoTUBER Tuberculin syringe	DD 1023663-1 NB 0197
dispoFINE Injection needle	Class IIa	dispoFINE Injection needle	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968A0101010102CK			
dispoGUARD Safety injection needle **Basic UDI-DI: 59079968A0101010101CH**	Class IIa	dispoGUARD Safety injection needle	DD 1023663-1 NB 0197
dispoSULIN Insulin pen needle **Basic UDI-DI: 59079968A010101026Q**	Class IIa	dispoSULIN Insulin pen needle	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set **Basic UDI-DI: 59079968A03010102-PHT66**	Class IIa	easyFLOW TS Transfusion set	DD 1023663-1 NB 0197
easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free **Basic UDI-DI: 59079968A030101027S**	Class IIa	easyFLOW TS Transfusion set, phthalate-free easyFLOW TS PREMIUM Transfusion set, phthalate-free	DD 1023663-1 NB 0197
NEEDLE FREE VALVE blue **Basic UDI-DI: 59079968A0705KE**	Class IIa	NEEDLE FREE VALVE blue	DD 1023663-1 NB 0197
NEEDLE FREE VALVE transparent **Basic UDI-DI: 59079968A07050295**	Class IIa	NEEDLE FREE VALVE transparent	DD 1023663-1 NB 0197
NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double NEEDLE FREE VALVE transparent with extension line, triple NEEDLE FREE VALVE transparent with extension line, quadruple **Basic UDI-DI: 59079968A070502-LCQ**	Class IIa	NEEDLE FREE VALVE transparent with extension line, single NEEDLE FREE VALVE transparent with extension line, double NEEDLE FREE VALVE transparent with extension line, triple NEEDLE FREE VALVE transparent with extension line, quadruple	DD 1023663-1 NB 0197

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
safeCARE Surgical gloves, latex, powdered **Basic UDI-DI: 59079968T01010101-RYM**	Class IIa	safeCARE Surgical gloves, latex, powdered	DD 1023663-1 NB 0197
safeCARE PF Surgical gloves powder free, sterile **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE PF Surgical gloves powder free, sterile	DD 1023663-1 NB 0197
safeCARE basic Surgical gloves latex, powdered **Basic UDI-DI: 59079968T01010101-RYM**	Class IIa	safeCARE basic Surgical gloves latex, powdered	DD 1023663-1 NB 0197
safeCARE basic PF Surgical gloves latex, powder-free **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE basic PF Surgical gloves latex, powder-free	DD 1023663-1 NB 0197
safeCARE premium Surgical gloves latex, powder-free **safeCARE UG Surgical gloves latex, powder-free** **safeCARE micro Surgical gloves latex, powder-free** **safeCARE ortho Surgical gloves latex, powder-free** **safeCARE dual Surgical gloves latex, powder-free** **Basic UDI-DI: 59079968T01010102-RYS**	Class IIa	safeCARE premium Surgical gloves latex, powder-free safeCARE UG Surgical gloves latex, powder-free safeCARE micro Surgical gloves latex, powder-free safeCARE ortho Surgical gloves latex, powder-free safeCARE dual Surgical gloves latex, powder-free	DD 1023663-1 NB 0197
safeCARE synthetic Surgical gloves neoprene, powder-free **safeCARE synthetic UG Surgical gloves neoprene, powder-free** **Basic UDI-DI: 59079968T010102-NRWL**	Class IIa	safeCARE synthetic Surgical gloves neoprene, powder-free safeCARE synthetic UG Surgical gloves neoprene, powder-free	DD 1023663-1 NB 0197
safeCARE fusion Surgical gloves polyisoprene, powder-free	Class IIa	safeCARE fusion Surgical gloves polyisoprene, powder-free	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968T010102-PRWS			
safeCARE virtuo Surgical gloves flexylon, powder-free **safeCARE virtuo UG Surgical gloves flexylon, powder-free** **safeCARE pro protect Surgical gloves flexylon, powder-free** **Basic UDI-DI: 59079968T010102-FRVU**	Class IIa	safeCARE virtuo Surgical gloves flexylon, powder-free safeCARE virtuo UG Surgical gloves flexylon, powder-free safeCARE pro protect Surgical gloves flexylon, powder-free	DD 1023663-1 NB 0197
safeLANCE Pressure-activated safety lancet **Basic UDI-DI: 59079968V0104RM**	Class IIa	safeLANCE Pressure-activated safety lancet	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-SETA**	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-SHTG**	Class IIa	deltaset Urinary bladder catheterization kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-CERS**	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-CHRY**	Class IIa	deltaset Dialysis kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-WETN**	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
deltaset Procedure kit O **Basic UDI-DI: 59079968V0599-WHTU**	Class IIa	deltaset Dressing change kit	DD 1023663-1 NB 0197
deltaset Procedure kit O	Class IIa	deltaset Suture application kit	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968V0599-RET7		deltaset Suture removal kit	
deltaset **Procedure kit O** **Basic UDI-DI: 59079968V0599-RHTD**	Class IIa	deltaset Suture application kit deltaset Suture removal kit	DD 1023663-1 NB 0197
deltaset **Procedure kit O** **Basic UDI-DI: 59079968V0599-IESC**	Class IIa	deltaset Anasthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
deltaset **Procedure kit O** **Basic UDI-DI: 59079968V0599-IHSJ**	Class IIa	deltaset Anasthesia kit deltaset Puncture kit	DD 1023663-1 NB 0197
elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile **elastoKIDS STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile** **Basic UDI-DI: 59079968T0305RB**	Class I devices placed on the market in sterile condition	elastopor STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile elastoKIDS STERIL Non-woven dressing with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
elastoDERM PAD **Foil dressing, with absorbent pad, self-adhesive, sterile** **Basic UDI-DI: 59079968M040101-FHU**	Class I devices placed on the market in sterile condition	elastoDERM PAD Foil dressing, with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
elastoSTRIP **Wound closure strips, sterile** **Basic UDI-DI: 59079968M040499FL**	Class I devices placed on the market in sterile condition	elastoSTRIP Wound closure strips, sterile	DD 1023663-1 NB 0197
UMBILICAL CORD CLAMP, sterile **Basic UDI-DI: 59079968V0202RN**	Class I devices placed on the market in sterile condition	UMBILICAL CORD CLAMP, sterile	DD 1023663-1 NB 0197
ALPHAtex Procedure gown NORMAL, sterile	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL, sterile	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968T0205R6			
ALPHAtex Procedure gown NORMAL-P **Basic UDI-DI: 59079968T0205R6**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown NORMAL-P, sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD, sterile **ALPHAtex Surgical gown COMFORT sterile** **Basic UDI-DI: 59079968T020401HA**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD, sterile ALPHAtex Surgical gown COMFORT sterile	DD 1023663-1 NB 0197
ALPHAtex Surgical gown CLASSIC-P **ALPHAtex Surgical gown STANDARD-P** **ALPHAtex Surgical gown COMFORT-P** **Basic UDI-DI: 59079968T020401HA**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown CLASSIC-P, sterile ALPHAtex Surgical gown STANDARD-P, sterile ALPHAtex Surgical gown COMFORT-P sterile	HD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile **ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile** **ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile** **Basic UDI-DI: 59079968T020402HC**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD PLUS, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE, with impermeable parts, sterile	DD 1023663-1 NB 0197
ALPHAtex Surgical gown STANDARD PLUS-P, with impermeable parts **ALPHAtex Surgical gown COMFORT PLUS-P, with impermeable parts** **ALPHAtex Surgical gown EXTRA SAFE-P, with impermeable parts** **Basic UDI-DI: 59079968T020402HC**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical gown STANDARD PLUS-P, with impermeable parts, sterile ALPHAtex Surgical gown COMFORT PLUS-P, with impermeable parts, sterile ALPHAtex Surgical gown EXTRA SAFE-P, with	HD 1023663-1 NB 0197

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
		impermeable parts, sterile	
ALPHAtex Surgical drape, sterile **ALPHAtex 2-layer surgical drape, with cellulose layer, sterile** **ALPHAtex 2-layer surgical drape, sterile** **ALPHAtex 2-layer surgical drape with adhesive edge, sterile** **ALPHAtex 2-layer surgical drape with central fenestration, sterile** **ALPHAtex 2-layer surgical drape with central adhesive fenestration, sterile** **ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile** **ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile** **ALPHAtex 3-layer surgical drape, sterile** **ALPHAtex 3-layer surgical drape with adhesive edge, sterile** **ALPHAtex 3-layer surgical drape with central fenestration, sterile** **ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile** **ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile** **Basic UDI-DI: 59079968T0201QW**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer surgical drape with central adhesive fenestration, sterile ALPHAtex 2-layer surgical drape with central, adjustable adhesive fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile ALPHAtex Reinforced surgical drape with adhesive fenestration, sterile	DD 1023663-1 NB 0197

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**
ALPHAtex Surgical drape **ALPHAtex 2-layer surgical drape, with cellulose layer** **ALPHAtex 2-layer surgical drape** **ALPHAtex 2-layer surgical drape with adhesive edge** **ALPHAtex 2-layer surgical drape with central fenestration** **ALPHAtex 2-layer surgical drape with central adhesive fenestration** **ALPHAtex 3-layer surgical drape** **ALPHAtex 3-layer surgical drape with adhesive edge** **ALPHAtex 3-layer surgical drape with central fenestration** **ALPHAtex 3-layer surgical drape with central adhesive fenestration** **Basic UDI-DI: 59079968T0201QW**	Class I devices placed on the market in sterile condition	ALPHAtex Surgical drape, sterile ALPHAtex 2-layer surgical drape, with cellulose layer, sterile ALPHAtex 2-layer surgical drape, sterile ALPHAtex 2-layer surgical drape with adhesive edge, sterile ALPHAtex 2-layer surgical drape with central fenestration, sterile ALPHAtex 2-layer epidural surgical drape with adhesive fenestration, sterile ALPHAtex 3-layer surgical drape, sterile ALPHAtex 3-layer surgical drape with adhesive edge, sterile ALPHAtex 3-layer surgical drape with central fenestration, sterile ALPHAtex 3-layer surgical drape with central adhesive fenestration, sterile	HD 1023663-1 NB 0197
ALPHAtex Instrument table cover, sterile **Basic UDI-DI: 59079968T030101-INJ**	Class I devices placed on the market in sterile condition	ALPHAtex Instrument table cover, sterile	DD 1023663-1 NB 0197
ALPHAtex Reinforced Mayo stand cover, sterile **ALPHAtex Reinforced Mayo stand cover, red, sterile** **Basic UDI-DI: 59079968T030101-MNS**	Class I devices placed on the market in sterile condition	ALPHAtex Reinforced Mayo stand cover, sterile ALPHAtex Reinforced Mayo stand cover, red, sterile	DD 1023663-1 NB 0197

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
ALPHAtex Armboard cover, sterile **ALPHAtex Surgical pocket for syringes, sterile** **Basic UDI-DI: 59079968T030101-NNU**	Class I devices placed on the market in sterile condition	ALPHAtex Armboard cover, sterile ALPHAtex Surgical pocket for syringes, sterile	DD 1023663-1 NB 0197
ALPHAtex Camera cables cover, sterile **ALPHAtex Circular banded cover for medical devices, sterile** **ALPHAtex Square banded cover for medical devices, sterile** **ALPHAtex C-arm cover set, sterile** **ALPHAtex Lamp handle cover, sterile** **ALPHAtex Ultrasound cover kits, sterile** **Basic UDI-DI: 59079968T030101-FNC**	Class I devices placed on the market in sterile condition	ALPHAtex Camera cables cover, sterile ALPHAtex Circular banded cover for medical devices, sterile ALPHAtex Square banded cover for medical devices, sterile ALPHAtex C-arm cover set, sterile ALPHAtex Lamp handle cover, sterile ALPHAtex Ultrasound cover kits, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile **ALPHAtex Absorbent drape for newborn, sterile** **Basic UDI-DI: 59079968T020199-SRU**	Class I devices placed on the market in sterile condition	ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile	DD 1023663-1 NB 0197
ALPHAtex Absorbent drape, sterile **ALPHAtex Absorbent drape for newborn, sterile** **Basic UDI-DI: 59079968T020199-SRU**	Class I devices placed on the market in sterile condition	ALPHAtex Absorbent drape, sterile ALPHAtex Absorbent drape for newborn, sterile	HD 1023663-1 NB 0197
ALPHAtex Limb cover, sterile **ALPHAtex Head Turban drape, sterile** **ALPHAtex Under buttocks drape, sterile** **Basic UDI-DI: 59079968T020102GV**	Class I devices placed on the market in sterile condition	ALPHAtex Limb cover, sterile ALPHAtex Head Turban drape, sterile ALPHAtex Under buttocks drape, sterile	DD 1023663-1 NB 0197
ALPHAtex Adhesive pouch, one-chamber, sterile	Class I devices placed on the	ALPHAtex Adhesive pouch,	DD 1023663-1 NB 0197

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**
ALPHAtex Adhesive pouch, two-chamber, sterile **ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile** **ALPHAtex Fluid collection pouch, cone-shaped, with outlet tip, sterile** **Basic UDI-DI: 59079968T020199-PRN**	market in sterile condition	one-chamber, sterile ALPHAtex Adhesive pouch, two-chamber, sterile ALPHAtex Arthroscopy fluid collection pouch, cone-shaped, with outlet tip, sterile ALPHAtex Fluid collection pouch, cone-shaped, with outlet tip, sterile	
ALPHAtex Non-woven surgical tape, adhesive, sterile **ALPHAtex Velcro surgical tape, sterile** **Basic UDI-DI: 59079968T020199-TRW**	Class I devices placed on the market in sterile condition	ALPHAtex Non-woven surgical tape, adhesive, sterile ALPHAtex Velcro surgical tape, sterile	DD 1023663-1 NB 0197
ALPHAtex Abdominal drape, sterile **ALPHAtex Abdo-Perineal drape, sterile** **ALPHAtex Angiography drape, sterile** **ALPHAtex Cardiology drape, sterile** **ALPHAtex Cardiac drape, sterile** **ALPHAtex C-section drape, sterile** **ALPHAtex Delivery drape, sterile** **ALPHAtex Extremity drape, sterile** **ALPHAtex Gynaecology drape, sterile** **ALPHAtex Laparoscopy drape, sterile** **ALPHAtex Ophthalmic drape, sterile** **ALPHAtex Orthopaedic drape, sterile** **ALPHAtex Shoulder drape, sterile** **ALPHAtex Vertical isolation drape, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal drape, sterile ALPHAtex Abdo-Perineal drape, sterile ALPHAtex Angiography drape, sterile ALPHAtex Cardiology drape, sterile ALPHAtex Cardiac drape, sterile ALPHAtex C-section drape, sterile ALPHAtex Delivery drape, sterile ALPHAtex Extremity drape, sterile ALPHAtex Gynaecology drape, sterile ALPHAtex Laparoscopy drape, sterile	DD 1023663-1 NB 0197

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
Basic UDI-DI: 59079968T0202QY		ALPHAtex Ophthalmic drape, sterile ALPHAtex Orthopaedic drape, sterile ALPHAtex Shoulder drape, sterile ALPHAtex Vertical isolation drape, sterile	
ALPHAtex Abdominal drape, sterile **ALPHAtex Abdo-Perineal drape, sterile** **ALPHAtex Angiography drape, sterile** **ALPHAtex Cardiology drape, sterile** **ALPHAtex Cardiac drape, sterile** **ALPHAtex C-section drape, sterile** **ALPHAtex Delivery drape, sterile** **ALPHAtex Extremity drape, sterile** **ALPHAtex Gynaecology drape, sterile** **ALPHAtex Laparoscopy drape, sterile** **ALPHAtex Ophthalmic drape, sterile** **ALPHAtex Orthopaedic drape, sterile** **ALPHAtex Shoulder drape, sterile** **ALPHAtex Vertical isolation drape, sterile** **Basic UDI-DI: 59079968T0202QY**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal drape (from 1 to 100) ALPHAtex Abdo-Perineal drape (from 1 to 100) ALPHAtex Angiography drape (from 1 to 100) ALPHAtex Cardiology drape (from 1 to 100) ALPHAtex Cardiac drape (from 1 to 100) ALPHAtex C-section drape (from 1 to 100) ALPHAtex Delivery drape (from 1 to 100) ALPHAtex Extremity drape (from 1 to 100) ALPHAtex Gynaecology drape (from 1 to 100) ALPHAtex Laparoscopy drape (from 1 to 100) ALPHAtex Ophthalmic drape (from 1 to 100) ALPHAtex Orthopaedic drape (from 1 to 100) ALPHAtex Shoulder drape (from 1 to 100)	HD 1023663-1 NB 0197

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
		ALPHAtex Vertical isolation drape (from 1 to 100)	
ALPHAtex Abdominal set, sterile **ALPHAtex Abdo-Perineal set, sterile** **ALPHAtex Ablation set, sterile** **ALPHAtex Angiography set, sterile** **ALPHAtex Arthroscopy set, sterile** **ALPHAtex Basic set, sterile** **ALPHAtex Cardiology set, sterile** **ALPHAtex Cardiac set, sterile** **ALPHAtex Craniotomy set, sterile** **ALPHAtex C-section set, sterile** **ALPHAtex Cystoscopy set, sterile** **ALPHAtex Delivery set, sterile** **ALPHAtex Dental set, sterile** **ALPHAtex Dynamic hip screw set, sterile** **ALPHAtex Extremity set, sterile** **ALPHAtex Gynaecology set, sterile** **ALPHAtex Hip set, sterile** **ALPHAtex Laparoscopy set, sterile** **ALPHAtex Laryngology set, sterile** **ALPHAtex Ophthalmic set, sterile** **ALPHAtex Otolaryngology set, sterile** **ALPHAtex Pediatric set, sterile** **ALPHAtex Percutaneous lithotripsy set, sterile** **ALPHAtex Shoulder set, sterile** **ALPHAtex Spine set, sterile**	Class I devices placed on the market in sterile condition	ALPHAtex Abdominal set, sterile ALPHAtex Abdo-Perineal set, sterile ALPHAtex Ablation set, sterile ALPHAtex Angiography set, sterile ALPHAtex Arthroscopy set, sterile ALPHAtex Basic set, sterile ALPHAtex Cardiology set, sterile ALPHAtex Cardiac set, sterile ALPHAtex Craniotomy set, sterile ALPHAtex C-section set, sterile ALPHAtex Cystoscopy set, sterile ALPHAtex Delivery set, sterile ALPHAtex Dental set, sterile ALPHAtex Dynamic hip screw set, sterile ALPHAtex Extremity set, sterile ALPHAtex Gynaecology set, sterile ALPHAtex Hip set, sterile ALPHAtex Laparoscopy set, sterile ALPHAtex Laryngology set, sterile	DD 1023663-1 NB 0197

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
ALPHAtex Thyroid set, sterile **ALPHAtex TUR set, sterile** **ALPHAtex Universal set, sterile** **ALPHAtex Uro/gynaecology set, sterile** **ALPHAtex Varicose vein set, sterile** **ALPHAtex Vertical isolation set, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Ophthalmic set, sterile ALPHAtex Otolaryngology set, sterile ALPHAtex Pediatric set, sterile ALPHAtex Percutaneous lithotripsy set, sterile ALPHAtex Shoulder set, sterile ALPHAtex Spine set, sterile ALPHAtex Thyroid set, sterile ALPHAtex TUR set, sterile ALPHAtex Universal set, sterile ALPHAtex Uro/gynaecology set, sterile ALPHAtex Varicose vein set, sterile ALPHAtex Vertical isolation set, sterile	
ALPHAtex Abdominal set, sterile **ALPHAtex Abdo-Perineal set, sterile** **ALPHAtex Ablation set, sterile** **ALPHAtex Angiography set, sterile** **ALPHAtex Arthroscopy set, sterile** **ALPHAtex Basic set, sterile** **ALPHAtex Cardiology set, sterile** **ALPHAtex Cardiac set, sterile** **ALPHAtex Craniotomy set, sterile** **ALPHAtex C-section set, sterile**	Class I devices placed on the market in sterile condition	"ALPHAtex Abdominal set (from 1 to 200) ALPHAtex Abdo-Perineal set (from 1 to 200) ALPHAtex Ablation set (from 1 to 200) ALPHAtex Angiography set (from 1 to 200) ALPHAtex Arthroscopy set (from 1 to 200) ALPHAtex Basic set (from 1 to 200) ALPHAtex Cardiology set (from 1 to 200)	HD 1023663-1 NB 0197

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
ALPHAtex Cystoscopy set, sterile **ALPHAtex Delivery set, sterile** **ALPHAtex Dental set, sterile** **ALPHAtex Dynamic hip screw set, sterile** **ALPHAtex Extremity set, sterile** **ALPHAtex Gynaecology set, sterile** **ALPHAtex Hip set, sterile** **ALPHAtex Laparoscopy set, sterile** **ALPHAtex Laryngology set, sterile** **ALPHAtex Ophthalmic set, sterile** **ALPHAtex Otolaryngology set, sterile** **ALPHAtex Pediatric set, sterile** **ALPHAtex Percutaneous lithotripsy set, sterile** **ALPHAtex Shoulder set, sterile** **ALPHAtex Spine set, sterile** **ALPHAtex Thyroid set, sterile** **ALPHAtex TUR set, sterile** **ALPHAtex Universal set, sterile** **ALPHAtex Uro/gynaecology set, sterile** **ALPHAtex Varicose vein set, sterile** **ALPHAtex Vertical isolation set, sterile** **Basic UDI-DI: 59079968T0202QY**		ALPHAtex Cardiac set (from 1 to 200) ALPHAtex Craniotomy set (from 1 to 200) ALPHAtex C-section set (from 1 to 200) ALPHAtex Cystoscopy set (from 1 to 200) ALPHAtex Delivery set (from 1 to 200) ALPHAtex Dental set (from 1 to 200) ALPHAtex Dynamic hip screw set (from 1 to 200) ALPHAtex Extremity set (from 1 to 200) ALPHAtex Gynaecology set (from 1 to 200) ALPHAtex Hip set (from 1 to 200) ALPHAtex Laparoscopy set (from 1 to 200) ALPHAtex Laryngology set (from 1 to 200) ALPHAtex Ophthalmic set (from 1 to 200) ALPHAtex Otolaryngology set (from 1 to 200) ALPHAtex Pediatric set (from 1 to 200) ALPHAtex Percutaneous lithotripsy set (from 1 to 200) ALPHAtex Shoulder set (from 1 to 200) ALPHAtex Spine set (from 1 to 200) ALPHAtex Thyroid set (from 1 to 200)	

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
		ALPHAtex TUR set (from 1 to 200) ALPHAtex Universal set (from 1 to 200) ALPHAtex Uro/gynaecology set (from 1 to 200) ALPHAtex Varicose vein set (from 1 to 200) ALPHAtex Vertical isolation set (from 1 to 200)"	
elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile **Basic UDI-DI: 59079968M040301-SKC**	Class I devices placed on the market in sterile condition	elastoLUMENAL S Eye pad, superabsorbent, multi-layer, sterile	DD 1023663-1 NB 0197
elastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile **Basic UDI-DI: 59079968M0403NX**	Class I devices placed on the market in sterile condition	lastopor EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile elastoKIDS EYE Eye dressing, non-woven, with absorbent pad, self-adhesive, sterile	DD 1023663-1 NB 0197
COMBI STOPPER **Basic UDI-DI: 59079968C01018085**	Class I devices placed on the market in sterile condition	COMBI STOPPER	DD 1023663-1 NB 0197
LUER LOCK STOPPER **Basic UDI-DI: 59079968C01018085**	Class I devices placed on the market in sterile condition	LUER LOCK STOPPER	DD 1023663-1 NB 0197
elastopor STERIL D Non-woven dressing with absorbent pad, with incision and O-hole, self-adhesive, sterile elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with	Class I devices placed on the market in sterile condition	elastopor STERIL D Non-woven dressing with absorbent pad, with incision and O-hole, self-adhesive, sterile elastopor STERIL D Non-woven	DD 1023663-1 NB 0197

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
incision and X-hole, self-adhesive, sterile **Basic UDI-DI: 59079968M04010201-DTG**		dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile elastoKIDS STERIL D Non-woven dressing, with absorbent pad, with incision and X-hole, self-adhesive, sterile	
NONVI lux S Non-woven swab, with O-incision, sterile **NONVI lux S Non-woven swab, with Y-incision, sterile** **Basic UDI-DI: 59079968M04010201-NU4**	Class I devices placed on the market in sterile condition	NONVI lux S Non-woven swab, with O-incision, sterile NONVI lux S Non-woven swab, with Y-incision, sterile	DD 1023663-1 NB 0197
elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile **elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile** **Basic UDI-DI: 59079968M04010201H2**	Class I devices placed on the market in sterile condition	elastopor IV IV cannula dressing, non-woven, selfadhesive, sterile elastoKIDS IV IV cannula dressing, non-woven, selfadhesive, sterile	DD 1023663-1 NB 0197
elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile **elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile** **elastoDERM Foil dressing, self-adhesive, sterile** **elastoDERM F Foil dressing, with frame, selfadhesive, sterile** **elastoDERM C Foil dressing with a pocket to secure catheter, sterile** **Basic UDI-DI: 59079968M04010202H4**	Class I devices placed on the market in sterile condition	elastoDERM F-IV IV cannula dressing, foil, with frame, with U-incision, self-adhesive, sterile elastoDERM IV IV cannula dressing, foil, selfadhesive, sterile elastoDERM Foil dressing, self-adhesive, sterile elastoDERM F Foil dressing, with frame, selfadhesive, sterile elastoDERM C Foil dressing with a pocket to secure catheter, sterile	DD 1023663-1 NB 0197

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**
MULTIabsorb S ABD pad, non-woven and cellulose, sterile **Basic UDI-DI: 59079968M040201-SJZ**	Class I devices placed on the market in sterile condition	MULTIabsorb S ABD pad, non-woven and cellulose, sterile	DD 1023663-1 NB 0197
VAGINAL SPECULUM **Basic UDI-DI: 59079968U089006MJ**	Class I devices placed on the market in sterile condition	VAGINAL SPECULUM	DD 1023663-1 NB 0197
URINE BAG **Basic UDI-DI: 59079968A0603038J**	Class I devices placed on the market in sterile condition	URINE BAG	DD 1023663-1 NB 0197
URINE BAG with sample port, sterile **URINE BAG with sample port 2W, sterile** **Basic UDI-DI: 59079968A060303-PBW**	Class I devices placed on the market in sterile condition	URINE BAG with sample port, sterile URINE BAG with sample port 2W, sterile	DD 1023663-1 NB 0197
SAMPLES TAKING URINE BAG for boys, with sponge **SAMPLES TAKING URINE BAG for boys, without sponge** **SAMPLES TAKING URINE BAG for girls, with sponge** **SAMPLES TAKING URINE BAG for girls, without sponge** **Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką** **Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką** **Basic UDI-DI: 59079968A06030301AB**	Class I devices placed on the market in sterile condition	SAMPLES TAKING URINE BAG for boys, with sponge SAMPLES TAKING URINE BAG for boys, without sponge SAMPLES TAKING URINE BAG for girls, with sponge SAMPLES TAKING URINE BAG for girls, without sponge Apteczka ABC Woreczek do pobierania próbek moczu dla dla chłopców z gąbką Apteczka ABC Woreczek do pobierania próbek moczu dla dziewczynek z gąbką	DD 1023663-1 NB 0197
ENEMA BAG sterile **Basic UDI-DI: 59079968G020301-SDY**	Class I devices placed on the market in sterile condition	ENEMA BAG sterile	DD 1023663-1 NB 0197

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**
WOODEN TONGUE DEPRESSOR Sterile **Basic UDI-DI: 59079968V9001-SNM**	Class I devices placed on the market in sterile condition	WOODEN TONGUE DEPRESSOR sterile	DD 1023663-1 NB 0197
NELATON CATHETER NELATON CATHETER transparent **Basic UDI-DI: 59079968U010105H9**	Class I devices placed on the market in sterile condition	NELATON CATHETER NELATON CATHETER transparent	DD 1023663-1 NB 0197
GUEDEL AIRWAY **Basic UDI-DI: 59079968R010102FG**	Class I devices placed on the market in sterile condition	GUEDEL AIRWAY	DD 1023663-1 NB 0197
ENDOTRACHEAL TUBE HOLDER, vertical fixation ENDOTRACHEAL TUBE HOLDER, horizontal fixation **Basic UDI-DI: 59079968R010380-SNX**	Class I devices placed on the market in sterile condition	ENDOTRACHEAL TUBE HOLDER, vertical fixation ENDOTRACHEAL TUBE HOLDER, horizontal fixation	DD 1023663-1 NB 0197
INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED **Basic UDI-DI: 59079968R010380-PNR**	Class I devices placed on the market in sterile condition	INTUBATION STYLET TRACHEAL TUBE INTRODUCER CURVED	DD 1023663-1 NB 0197
dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter **Basic UDI-DI: 59079968A0704KC**	Class I devices placed on the market in sterile condition	dicoSPIKE Withdrawal cannula with bacteria filter dicoSPIKE Withdrawal cannula with bacteria and particle filter dicoSPIKE Chemo Withdrawal cannula with bacteria and particle filter	DD 1023663-1 NB 0197
elastoBAND BASIC S KnItted supporting bandage, sterile **Basic UDI-DI: 59079968M030301-SJT**	Class I devices placed on the market in sterile condition	elastoBAND BASIC S KnItted supporting bandage, sterile	HD 1023663-1 NB 0197
elastoBAND FLEX S Elastic bandage, sterile	Class I devices placed on the	elastoBAND FLEX S	DD 1023663-1 NB 0197

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**
Basic UDI-DI: 59079968M030402-SKB	market in sterile condition	Elastic bandage, sterile	
elastoFILM Incise film, self-adhesive, sterile **elastoFILM M Incise film, self-adhesive, sterile** **Basic UDI-DI: 59079968T020101GT**	Class I devices placed on the market in sterile condition	elastoFILM Incise film, self-adhesive, sterile elastoFILM M Incise film, self-adhesive, sterile	DD 1023663-1 NB 0197
CERVICAL BRUSH standard **CERVICAL BRUSH special** **Basic UDI-DI: 59079968U090303L7**	Class I devices placed on the market in sterile condition	CERVICAL BRUSH standard CERVICAL BRUSH special	DD 1023663-1 NB 0197
omegapack Surgical set B **Basic UDI-DI: 59079968V0599-EP2**	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
omegapack Surgical set B **Basic UDI-DI: 59079968V0599-KPE**	Class IIb excluding Class IIb implantable non-WET	omegapack Surgical set B Orthopedic surgery set B Universal set B Surgical set B Orthopedic surgery set B Universal set B	HD 1023663-1 NB 0197
omegapack Surgical set **Basic UDI-DI: 59079968V0599-ANS**	Class IIa	omegapack Surgical set Angiography set C-section set Laparoscopy set Gynecological surgery set Cardiac surgery set Neurosurgical set Orthopedic surgery set Otolaryngologic surgery set Urologic surgery set Delivery set Dressing set	HD 1023663-1 NB 0197

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
		Universal set	
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-WQ6**	Class IIa	deltaset Central venous access kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-IPA**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-CNW**	Class IIa	deltaset Dialysis kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-NPL**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-OPN**	Class IIa	deltaset Universal kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-FP4**	Class IIa	deltaset Urinary bladder catheterization kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-RPU**	Class IIa	deltaset Sewing kit Suture removal kit Dressing change kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-SPW**	Class IIa	deltaset Anasthesia kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-NIT3**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-UITQ**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197

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
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-BIRX**	Class I devices placed on the market in sterile condition	deltaset Dialysis kit	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-MISY**	Class I devices placed on the market in sterile condition	deltaset Universal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-DIS5**	Class I devices placed on the market in sterile condition	deltaset Operating field disinfection kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-ZIU7**	Class I devices placed on the market in sterile condition	deltaset Suture removal kit I	HD 1023663-1 NB 0197
deltaset Procedure kit **Basic UDI-DI: 59079968V0599-PIT9**	Class I devices placed on the market in sterile condition	deltaset Protective kit I Hygiene kit I Neonatal kit I	HD 1023663-1 NB 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
none			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/15	ZARYS_CL607_2024-05-15	Initial issue

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139535 0001

Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

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

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs
  (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges
  (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls
  (with or without X-ray thread)
- Sterile and non-sterile gauze rolls
  (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
  (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 2/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 3/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 4/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannulla fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 5/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer:
ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Notifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

TÜVRheinland®

Doc. 6/6, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60139535 0001
Report No.: 26300232 017

Manufacturer: ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Poland

Activity: Production

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-05-27

Rafal Byczkowski

CE sertifikatas
93/42/EEC Direktyva V Priedas
Gamybos kokybės užtikrinimas
Medicinos prietaisai

Registracijos Nr.: DD 60139535 0001

Ataskaitos Nr.: 26300232 017

Gamintojas: Zarys International Group
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Produktai: (Žr. Priedus dėl produktų ir įtrauktų vietų)
Pakeičia CE sertifikatą Nr. DD 60100191 0001

Galioja iki: 2024-05-27

Notifikuota įstaiga patvirtina minėtos įmonės įdiegtą ir taikomą kokybės valdymo sistemą. Direktyvos 93/42/EEB V Priedo reikalavimai buvo įvykdyti. Minėtas gamintojas yra įdiegės ir taiko kokybės užtikrinimo sistemą, kuri yra periodiškai tikrinama, pagal minėtos direktyvos V Priedo 4 skyrių. IIb ir III klasės prietaisų, minimų šiame sertifikate, perkėlimui į rinką būtinas EB tipo patikros sertifikatas pagal III Priedą.

Galioja nuo: 2019-06-09

Notifikuota įstaiga

/parašas/ /antspaudas/

Data: 2019-05-27

Rafal Byczkowski

TÜV Rheinland LGA Products GmbH – Tillystrasse 2 – 90431 Nürnberg

TÜV Rheinland LGA Products GmbH yra Notifikuota įstaiga pagal Direktyvą 93/42/EEB dėl medicinos prietaisų, kurios identifikavimo numeris: 0197.

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterili ir nesterili kerpama marlė
- Nesterilūs marliniai tvarsčiai
- Sterilus/nesterilus marlinis tvarstis

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs marlės rutuliai

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs marlės ritiniai

(su/be rentgenokontrastine linija)

- Sterilūs ir nesterilūs neaustinės medžiagos tvarsčiai

(su/be rentgenokontrastine linija)

- Sterilūs parafininiai tvarsčiai
- Sterilūs trijų krypčių kraneliai
- Sterilios vienkartinės transfuzinės sistemos
- Sterilios vienkartinės infuzinės sistemos
- Sterilios prailginimo linijos infuzinėms pompoms

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterilūs endotrachėjiniai vamzdeliai
- Sterilūs tracheostominiai vamzdeliai
- Sterilio kvėpavimo grandinės
- Sterilūs prailgintojai prie intub. Vamzdelio
- Sterilios laringinės kaukės
- Sterilios deguonies kaukės
- Sterili kaukė su rezervuaru
- sterili aerozolinė kaukė
- Sterlios nosies deguonies kaniulės
- Sterilūs aerozoliniai rinkiniai
- Sterilūs deguonies vamzdeliai
- Sterilūs atsiurbimo kateteriai
- Sterilūs chirurginiai atsiurbimo rinkiniai
- Sterilios chirurginės atsiurbimo kaniulės
- Sterilūs maitinimo zondai
- Sterilūs skrandžio ir duodenaliniai zondai
- Sterilūs urologiniai kateteriai
- Sterilūs vienkartiniai švirkštai

Data: 2019-05-27 **Notifikuota įstaiga**

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:

- Sterilūs insulininiai švirkštai
- Sterilūs tuberkuliniai švirkštai
- Sterilios hipoderm· nės adatos
- Sterilios insulininių penų adatos
- Sterilūs kraujo lancetai
- Sterilios intraveninės kaniulės
- Sterilūs beadatiniai vožtuvai
- Sterilios chirurginės pirštinės

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Žemiau nurodytiems medicinos prietaisams reikalavimai taikomi tik gamybos aspektams, susijusiems su sterilių sąlygų kūrimų bei išlaikymu:

- Lipnus kaniulių fiksatoriai
- Lipnūs žaizdų tvarsčiai
- Akių tamponėliai
- Pjūvio juosta
- Permatomi juostiniai tvarsčiai
- Putų tvarsčiai
- Absorbuojantys žaizdų tvarsčiai
- Chirurginiai chalatai
- Chirurginiai dangalai
- Skysčių rinkimo talpos
- Nelaton kateteriai

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
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TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60117020 0001**

Ataskaitos Nr.: **26300232 005**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtraukti Produktai:
Žemiau nurodytiems medicinos prietaisams reikalavimai taikomi tik gamybos aspektams, susijusiems su sterilių sąlygų kūrimų bei išlaikymu:

- Vaginalinės spekulės
- Gimdos kaklelio šepetėliai
- Šlapimo maišeliai
- Liežuvio prispaudėjai
- Orofaringiniai vamzdeliai
- Intubaciniai stiletai
- Tracheostominio vamzdelio laikikliai
- Atsiurbimo vamzdeliai
- Ištraukimo kaniulės
- Alignato tvarsčiai
- Kaniulių kamštukai
- Umbilikaliniai spaustukai

Data: 2019-05-27 **Notifikuota įstaiga**

/parašas/ /antspaudas/

Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: **DD60139535 0001**

Ataskaitos Nr.: **26300232 017**

Gamintojas: **Zarys International Group**
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Lenkija

Įtrauktos vietos:

Zarys International Group
Spolka z organiczona
odpowiedzialnoscia
spolka komandytowa
ul. Gustawa Eiffel'a 15
44-109 Gliwice
Lenkija

Data: 2019-05-27

Notifikuota įstaiga

/parašas/ /antspaudas/
Rafal Byczkowski