

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-üyelik şirket
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KDV Tescil No

Tercüme edilmek üzere
dilindeki (ASİ...) tam ve doğru olarak
YEMİNLİ TERCÜMAN:

İstanbul
ANKARA
2023

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

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

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

Cihaz adı VEYA Temel UDI-DI (MDR başvurusu kapsamında)	MDR Cihaz sınıflandırması (başvuru öncesi aşamada imalatçı tarafından önerilen ve teyit edilen)	MDR cihazı bir yedek cihaz ise, mütakabil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
YUMUŞAK DREN 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 SETİ/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
YANKAUER ASPİRASYON BAĞLANTI HORTUMU/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
BIYOPSI PUNCH/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
GUEDEL AIRWAY/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
SOLUNUM EGZERSİZ CİHAZI ÜÇ TOPLU /	IIA	Aynı	1984-MDD-11-104 Kiwa Belgelendirme Hizmetleri A.Ş.



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KDV Tescil No:

Tercüme edilmek
dilindeki
tam ve doğru olarak
YEMİNLİ TERCÜMA



oda lgham
ay / ANKARA
00: 202 21 22

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, müteakibil MDD'nin tanımı	MDR başvurusu kapsamında cihazların MDD Sertifika Referans(lar)ı ve OK Tanımı
ASPIRASYON TORBASI, NON STERİL/ ASPIRASYON TORBASI / ASPIRASYON KANİSTERİ/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ASPIRASYON TORBASI HORTUMU/ KAPKON KONNEKTÖR/	IS	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
UZATMA HATTI/	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
NEPHROFLEX® BALON DİLATÖR / NEPHROFLEX® BALON DİLATÖR VE ŞİŞİRME CİHAZI /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.
ANESTEZİ DEVRESİ KORUGE/ ANESTEZİ DEVRESİ SMOOTHBORE/ ANESTEZİ DEVRESİ AYARLANABİLİR/ SOLUNUM DEVRESİ KORUGE/ SOLUNUM DEVRESİ SMOOTHBORE / SOLUNUM DEVRESİ AYARLANABİLİR/ SOLUNUM DEVRESİ IPPB/ SOLUNUM DEVRESİ KOAKSİYEL/ SOLUNUM DEVRESİ TRANSPORT/ SOLUNUM DEVRESİ IPPB YARI KAPALI SİSTEM / KATETER MOUNT KORUGE ÇİFT YÖNLÜ DÖNER BAŞLIKLİ / KATETER MOUNT SMOOTHBORE ÇİFT YÖNLÜ DÖNER BAŞLIKLİ /	IIA	Aynı	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.



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

Tercüme edilmiş ve
dijitaldeki (BBL) bilgileri
tam ve doğru olarak
YEMİNLİ TERCÜMANI




İk. Moda İşhanı
Kızılay / ANKARA
97 Faks: 425 47 83

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



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 KDV Tescil No: 00627711203 Vergi KN 03502820370 - Hi

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



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Tercüme edilen
dilindeki
tam ve doğru
YEMİNLİ TERCİ



Okge Sk. Moda İşhanı
/110 Kızılay / ANKARA
7 99 67 Fax: 425 47 88

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



Kiwa Cermet Italia S.p.A. - Kiwa Italia Holding Srl'nin yönetim ve koordinasyonuna tabi tek-üyelik şirkettir
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KDV Tescil No: 00627711203

Tercüme editme
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YEMİNLİ TERCÜME



r Cad. Menekşe Sk. Moda İşhanı
1. Kat No: 21/110 Kızılay / ANKARA
0 312 47 47 47 - 0 312 47 47 47

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



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

Tercüme edilmek
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YEMİNLİ TERCÜME



Kışe Sk. Moda İşhanı
/110 Kızılay / ANKARA
T: 0312 425 47 83

Esteemed

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

Notified Body Confirmation Letter Reference: CERBO0430223

To whom it may concern,

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

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

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

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

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

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



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nd coordination of Kiwa Italia Holding Srl



ik. Moda İşleri
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

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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.

Kiwa Cermet Italia S.p.A. – Single-member company subject to management and coordination of Kiwa Italia Holding Srl
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 Tel. +39.051.4593.111 - Fax +39.051.763.382 - info@kiwacermet.it - www.kiwa.it
 VAT Registration No. 006277112



oda ishan
 / ANKARA
 0312 444 444



Device name OR Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DILATOR W/ INFLATION DEVICE			
ANESTHESIA CIRCUIT CORRUGATED / ANESTHESIA CIRCUIT SMOOTHBORE / ANESTHESIA CIRCUIT EXTENDABLE / BREATHING CIRCUIT CORRUGATED / BREATHING CIRCUIT SMOOTHBORE / BREATHING CIRCUIT EXTENDABLE / BREATHING CIRCUIT IPPB / BREATHING CIRCUIT COAXIAL / BREATHING CIRCUIT TRANSPORT / BREATHING CIRCUIT IPPB SEMI CLOSED SYSTEM / CATHETER MOUNT CORRUGATED W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT SMOOTHBORE W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT EXTENDED W/ DOUBLE SWIVEL ELBOW / CATHETER MOUNT CORRUGATED / CATHETER MOUNT SMOOTHBORE / CATHETER MOUNT EXTENDED / BREATHING TRACHEOSTOMY CIRCUIT / TRACHEOSTOMY CIRCUIT T CONNECTOR / ANESTHESIA CIRCUIT CORRUGATED, STERILE / ANESTHESIA CIRCUIT SMOOTHBORE, STERILE / ANESTHESIA CIRCUIT EXTENDABLE, STERILE / BREATHING CIRCUIT CORRUGATED, STERILE / BREATHING CIRCUIT SMOOTHBORE, STERILE /	IIA	Same	1984-MDD-11-100 Kiwa Belgelendirme Hizmetleri A.Ş.



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 VAT Registration No. 0062771121



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


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 Tel. +39.051.4593.111 - Fax +39.051.763.382 - info@kiwacermet.it - www.kiwa.it
 VAT Registration No. 00627711203 – Tax ID 03502820370 – Share capital € 1.000.000,00

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 S.p.A. – Single-member company subject to management and coordination of Kiwa Italia Holding Srl
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 VAT Registration No. 00627711203 – Tax ID 03502820370 – Share capital: € 1.000.000,00 i.v.

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

Confirmation Letter Revision History

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

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





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

100
TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI



Number: E-61749811-511.99-1374208

Subject: About the Announcement Application Numbered 2023/KK-1

05.02.2024

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

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

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

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

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

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

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

I kindly request your information and necessary

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

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

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tam ve doğru olarak çevir
YEMİNLİ TERCÜMAN :

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Sıh / ANKARA
Fax: 423 47 83



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



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

05.02.2024

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

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

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

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

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

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

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

Bilgilerinizi ve gereğini rica ederim.

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

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

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Bu belge

Belge Doğrulama Kodu: 0ZW56ZW56ZW56ak1UZmxXZ

Belge Durum Durumu: <https://www.turkiye.gov.tr/saglik-titck-ebys>

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

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Kep Adresi: titck@hs01.kep.tr





EC Certificate

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

Certificate Number: 1984-MDD-11-100

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

Organization:

PLASTİ-MED PLASTİK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

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

The products defined at the enclosure which is the part of this certificate and contains 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

CERTIFICATE



Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

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

MURTEŞEM GOKHAN YUCEI

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:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

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
Malecot Nephrostomy Catheter And Sets	Occlusion Balloon Catheter
	Malecot Nephrostomy Catheter and Sets
Nephrostomy Catheter And Sets	Re-Entry Malecot Catheter
	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



Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;

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
Spirometer Filters	Round Silicone Drains
	Eliptic Mouth
	Circular Mouth
	Graded Mouth - Cartoon Mouth
Yankauer Suction Sets And Accessories	Circular Mouth - Cartoon Mouth
	Yankauer Suction Sets
	Yankauer Suction Handles
Biopsy Punch	Aspirator Connecting Tube
	230101
	230102
	230103
	230104

16 July 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

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
Smear Brush	HME Filter- Elite
	Smear Brush
	Smear Brush Endocervical

16 July 2020, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

Concerned medical devices;
Sterile medical devices

Product Name	Types
Karman Cannula	240111
	240112
	240113
	240114
	240115
	240116
	240117
	240118
	240119
Suction Bag & Canister And Accessories	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

Muhteşem Gökhan Yücel
Head of Notified Body



CERTIFICATE

Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

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

Head of Notified Body



CERTIFICATE

Enclosure of the EC Certificate:

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Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-11-100, Revision Number: 10

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 Multilength 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

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

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;

Non - Sterile medical devices

Product Name	Types
Disposable Air Cushion Mask	Neonatal
	Infant
	Pediatric
	Child
	Small Adult
	Adult
Silicone Mask	Neonatal
	Infant
	Pediatric
	Child
	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 Accessories	Suction Bags
	Suction Canister
Breathing And Anesthesia Circuits	Breathing Circuits
	Anesthesia Circuits
	Catheter Mount
	Breathing Inhalation- Treatment 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

MARUÇEHAN GÜRKAN TUCER
Head of Notified Body



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 kokybės sistemos 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 SİRKETİ

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

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

Sertifikatas 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


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/

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“ drenavimo kateteriai ir rinkiniai su užraktu ir adata

/parašas/



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
Spirometriniai filtrai	Apvalūs silikono drenai
	Elipsinė anga
	Apvali anga
	Graduota anga – multiplikacinė anga
Yankauer atsiurbimo rinkiniai ir priedai	Apvali anga – multiplikacinė anga
	Yankauer atsiurbimo rinkiniai
	Yankauer atsiurbimo rankenos
Odos biopsijos adatos	Aspiratoriaus jungiamasis vamzdis
	230101
	230102
	230103
	230104

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel
Notifikuotos įstaigos vadovas



CE Sertifikato Priedas

Puslapis 4/8

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
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



CE Sertifikato Priedas

Puslapis 6/8

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
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
	Prailgintoias 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



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/



CE Sertifikato Priedas

Puslapis 8/8

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:
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 prietaisų Tarybos Direktyvą 93/42/EEC su identifikacijos numeriu: 1984

/parašas/

Liepos 16 d. Stambulas, Turkija

Muhtesem Gokhan Yucel
Notifikuotos įstaigos vadovas

EU Quality Management System Certificate

Certificate no.:
0521GB448231026

Final Assessment Report No.:
0521AU35F

Effective date:
2023-10-26

Expiry date:
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
DNV MEDCERT
Pilatuspool 2,



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 validity of this certificate, contact info@medcert.de

Lorenz Runge
Chief Certification

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

820111 EN Rev. 4 2022.10.17



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



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.



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: 2023-11-16
Our reference: QS-0521

Notified Body Confirmation Letter
Certification No: 0521GB454231116

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 Nando¹, 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.

Primed Halberstadt Medizintechnik GmbH
Straße des 20. Juli 1
38820 Halberstadt
Germany
SRN²: DE-MF-000004967

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.

Page 2 of 5

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)

H

Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history



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
Brachytherapy radiation instruments	Class IIb implantable non-WET device	N/A	Certificate 0521GB410200424; NB 0482
Vacuum and gravity drainage systems	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Glutaraldehyde for the disinfection of medical devices	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy inner cannulas	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 0521GB410200424; NB 0482
Gastrointestinal tubes - other	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Ciaglia tracheostomy kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Griggs tracheostomy kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laryngectomy cannulas and kits, uncuffed	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laryngectomy cannulas - accessories	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Marking tapes, vascular structures	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Vacuum and gravity drainage systems	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Air/oxygen masks and nasal cannulas	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Intra- and postoperative blood collection and reinfusion only devices and kits	Class IIa	N/A	Certificate 0521GB410200424; NB 0482

Autologous blood collection bags	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Surgical drainage connection medical tubes	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Arthroscopy devices, single use - other	Class IIa	N/A	Certificate 0521GB410200424; NB 0482
Tracheostomy and laryngectomy cannulas - accessories	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Vacuum and gravity drainage systems	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Surgical drainage systems - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Tracheostomy dressings	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Respiratory suction probes	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Adapters and connectors	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Gastrointestinal lavage, tubes and sets - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Collection bags and other containers for drainages and fistulas, single use	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Mucous aspirators	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Devices for colorectal diagnostic procedures	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Fluid collection bags and systems - other	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Drainage and fluid collection devices - accessories	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482

Thoracentesis and paracentesis drainages and kits	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Surgical drainage connection medical tubes	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482
Collection bags and other containers for drainages and fistulas, single use	Class I devices placed on the market in sterile condition	N/A	Certificate 0521GB415200424 NB 0482

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
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2023-10-26	0521GB454231026	Initial issue
2023-10-30	0521GB454231030	Correction of MDD/AIMDD Certificate Reference(s) of the devices under MDR application and adding Class I devices placed on the market in sterile condition
2023-11-16	0521GB454231116	Removing 1 IIa device (C01901202) and adding 5 Class IIa devices and 2 Class I devices placed on the market in sterile condition

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

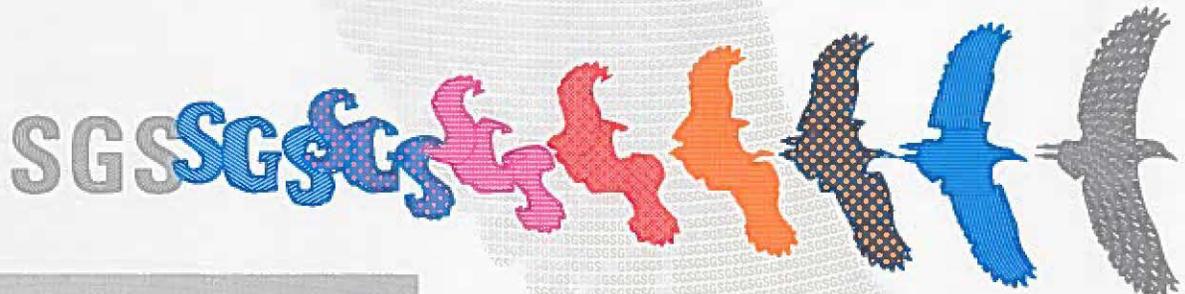


SGS Belgium NV, Notified Body 1639

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

LPMD5007 - Certificate CE1639 Annex II-4_EN rev 02

Page 1 of 3



Teleflex Medical

Directive 93/42/EEC

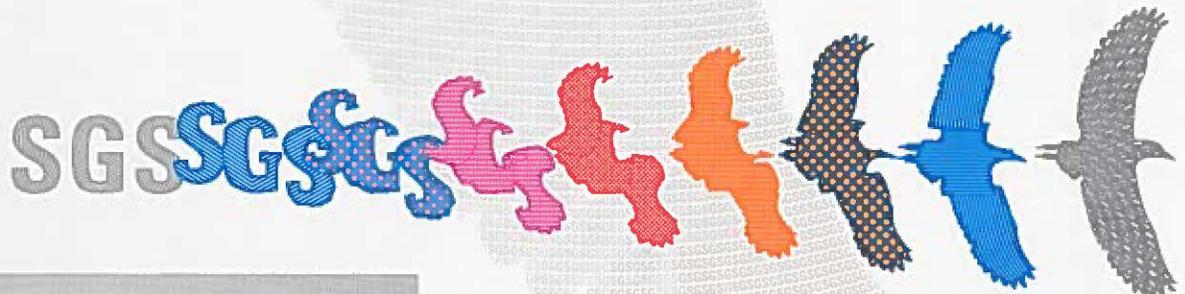
on medical devices, Annex II (excluding Section 4).

Issue 2

Detailed scope

- Sterile Hem-o-lok and Vesolock Ligation Clips,**
- Sterile and non-sterile Hemoclip Traditional, Hemoclip Plus, Horizon and Vesoclude**
- 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 closure system (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

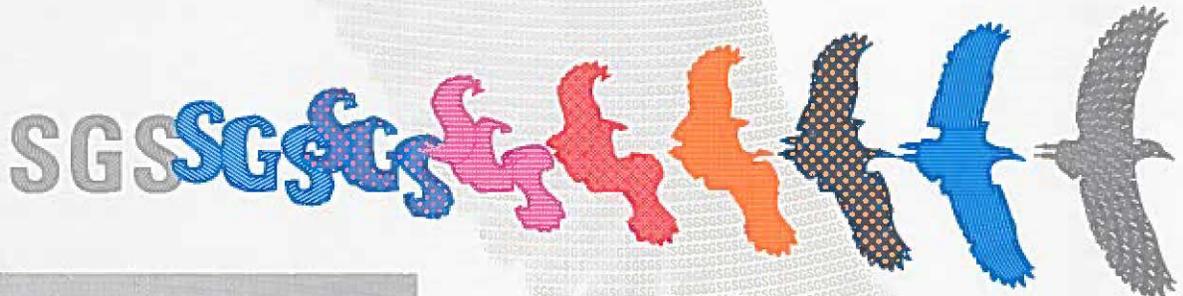
Detailed scope

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 pirmą 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

1 puslapis iš 3

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
Vesoclude
metalinės kabutės. Sterilūs Deknatel PTFE lopeliai.
Sterilūs nesirezorbuojantys poliesterio siūlai (POLYLENE/ „cotony“ II,
„silky“ II POLYDEK, TEVDEK, NextStich, Capiro, 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**

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 cholangiogramos 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 MiniGrip 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

puslapis 3 iš 3

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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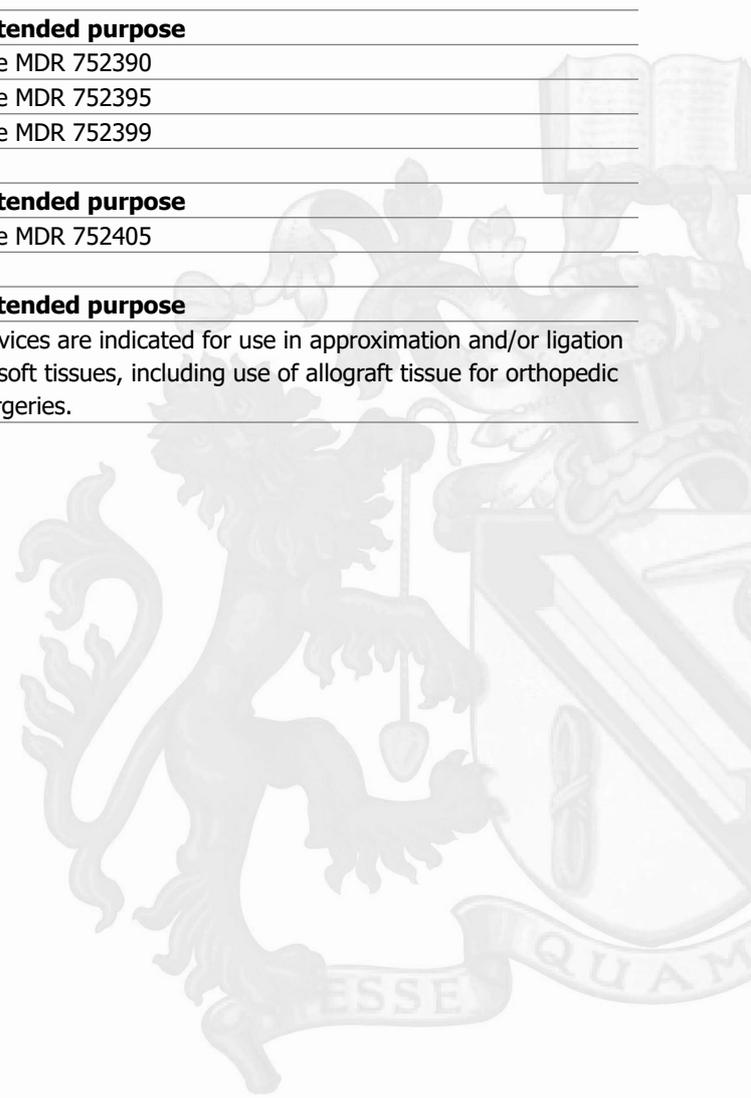
EU Quality Management System Certificate

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	<u>Name:</u> Teleflex Medical Inc. <u>Address:</u> 3015 Carrington Mill Blvd Morrisville, NC 27560 USA <u>Single Registration Number (SRN):</u> US-MF-000023660
Authorized Representative	<u>Name:</u> Teleflex Medical <u>Address:</u> IDA Business and Technology Park Dublin Road Athlone Co. Westmeath Ireland <u>Single Registration Number (SRN):</u> IE-AR-000015869
Notified Body	<u>Name:</u> BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands <u>Identification Number:</u> 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 000000009KA	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 000000009KA	Weck™ Hem-o-lok™ L, XL Take Apart 10 mm Endoscopic Clip Remover	544130T	L21		04/2007
0801902000000 000000009KA	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	<u>Manufacture:</u> Tecomet, Inc. 5307 95th Avenue Kenosha, Wisconsin 53144, USA <u>Refurbishment:</u> 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.
0801902000000 0000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, 70° Jaw, 11" (28 cm), Refurbished	544179R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 8" (20 cm), Refurbished	544180R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ L Ligating Clip Applier, Curved Jaw, 11" (28 cm), Refurbished	544181R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ L Conduit Ligating Clip Applier, 70° Angle Jaw, 11" (28 cm), Refurbished	544182R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ XL Ligating Clip Applier, Curved Jaw, 11" (28 cm), Refurbished	544191R	L020801		06/2012
0801902000000 0000000091KM	Weck™ Hem-o-lok™ XL Ligating Clip Applier, 70° Angled Jaw, 11" (28 cm), Refurbished	544192R	L020801		06/2012
0801902000000 0000000092KP	Weck™ Hem-o-lok™ S Open Remover, Straight Jaw, 8" (20 cm), Refurbished	544122R	L21		<u>Manufacture:</u> Tecomet, Inc. 5307 95th Avenue Kenosha, Wisconsin 53144, USA <u>Refurbishment:</u> Medical Specialties Inc. (MSI) 3874 South Alston Avenue Suite 103 Durham, NC 27713, USA
0801902000000 0000000092KP	Weck™ Hem-o-lok™ M, ML, L Open Clip Remover, Straight Jaw, 11" (28 cm), Refurbished	544123R	L21	06/2012	
0801902000000 0000000092KP	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