CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-682

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:

Medbar Tıbbi Malzemeler Turizm San. Ve Tic. A.Ş.

Fatih Mah. 1142 Sokak Sarnıç No:35 Gaziemir - İzmir - Turkey

Products: IV Flow Controller, Extension Line, Karman Cannula and Karman Cannula Injector, Arthroscopy Set, Spirometer Filtered Mouthpiece, Skin Marking Set, Mucous Aspirator, Valve Urine Bag, Valve Emesis Bag, Surgical Covers and Drapes, Endoscopy Mouthpiece, Smear Brushes, Amniotic Pouch Perforator, Umbilical Cord Clamp, Sterile Luer Connector Cap (Stopper), Arterial Cannula, Endometrial Suction Curette, Phototherapy Eye Band (Y-Band)

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.5746.03
Date of first issue: 13 July 2020
Date of last issue: 11 May 2021
Revision Number: 01
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.

Muhteşem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

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-20-682, Revision Number: 01

Concerned medical devices;

Product Name	Types
IV Flow Controller	IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
	Cylindrical IV Flow Controller (Long, Rotary Luer Lock, Without Y Port, Needle Free)
Extension Line	Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
	Pressure Resistant Extension Line (30cm- 50cm- 60cm- 75cm- 90cm- 100cm- 120cm- 150cm)
Karman Cannula and Karman Cannula Injector	Karman Cannula (No: 3, 4, 5, 6, 7, 8, 9, 10,12)
	Single Valve Manual Vacuum Aspirator Set, Double Valve Manual Vacuum Aspirator Set, Single Valve Manual Vacuum Aspirator, Double Valve Manual Vacuum Aspirator
	Non-Sterile Single Valve Manual Vacuum Aspirator, Non-Sterile Double Valve Manual Vacuum Aspirator
Arthroscopy Set	Y-Tur Set, Y-Tur Set With Pump
Spirometer Filtered Mouthpiece	Small (26mm, 30mm, 33mm)
	Small With Latch (26mm, 30mm, 33mm)
	Big (30mm, 33mm)
	Big With Latch (30mm, 33mm)
Skin Marking Set	Skin Marking Set, Thin Tipped Skin Marking Set
Mucous Aspirator	Mucous Aspirator (15ml, 25ml, 40ml, 100ml)
	Mucous Aspirator With Hose (40ml)
Valve Urine Bag	White, With Discharge
Valve Emesis Bag	Transparent, White
Surgical Covers and Drapes	Microscope Drape, Camera Cover, Cardboard Camera Cover, Telescopic Camera Cover, Circled Camera Cover, Accordion Folded Camera Cover, Probe Cover, Endoscopy Bag, Scopy Cover, C Arm Scopy Cover, Fluoroscopy Cover, Light Handle Cover
Endoscopy Mouthpiece	-
Smear Brushes	Brush, Spatula
Amniotic Pouch Perforator	-
Umbilical Cord Clamp	-
Sterile Luer Connector Cap (Stopper)	-
Arterial Cannula	18G, 20G, 22G
Endometrial Suction Curette	Endometrial Suction Curette, Endometrial Suction Curette With Syringe
Phototherapy Eye Band (Y-Band)	Small, Medium, Large

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

Muhteşem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.
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MDCG 2020-3 DEĞİŞİKLİK DOĞRULAMA FORMU
MDCG 2020-3 Change Verification Form

Tarih: *Date:*	16.06.2022
Referans No: *Reference No:*	MY-22-002237

Sayın Yetkili,

Tıbbi Cihaz Yönetmeliği ((AB) 2017/745) Madde 120 ve MDCG 2020-3 MDD veya AIMDD uyarınca düzenlenen sertifikaların kapsadığı cihazlarla ilgili olarak MDR Madde 120'de tanımlanan geçiş hükmünde belirtilen önemli değişikliklere ilişkin rehber dokümanına göre tarafımıza bildirilen aşağıdaki değişiklik önerisi incelenmiştir.

Dear Sir/Madam,

Your following proposed change is reviewed according to the MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

EC Sertifika Bilgileri *Information on EC Certificate*	
EC Sertifika No: *EC Certificate No:*	1984-MDD-20-682
Revizyon bilgileri: *Revision:*	1984-MDD-20-682 Rev.01 (11.05.2021)
İmalatçı : *Manufacturer:*	MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ
Son Geçerlilik Tarihi: *Expiry Date:*	27.05.2024
Değişiklik Önerisine İlişkin Bilgiler *Information on Proposed Change*	
Değişiklik konusu: *Subject of Change:*	"Valfli Kusmuk Torbası" ürününün EC sertifikası kapsamından çıkartılması" *"Valve Emesis Bag" product is removed from the scope of EC certificate*

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ tarafından önerilmiş olan yukarıdaki değişikliğin uygulanması MDR Madde 120(3) kapsamında tasarım ve kullanım amacında önemli değişiklik oluşturmamaktadır.

The implementation of the above change proposed by MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ does not represent a significant change in the design and usage purpose within the scope of MDR Article 120(3).

Yukarıda belirtilen EC sertifikası son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir.
The above-mentioned EC certificate is valid until its expiration date and is subject to the successful completion of periodic surveillance audits.

Bu yazı yukarıda belirtilen EC Sertifikası ile beraber sunulduğunda geçerlidir.
This letter is valid when presented together with the EC Certificate mentioned above.

Saygılarımızla / *Sincerely,*

Kiwa İSTANBUL TÜRKİYE

Orhan Karakuş
Kalite Müdürü / *Quality Manager*

Kiwa Belgelendirme Hizmetleri A.Ş.
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