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

Digitally signed by Iarovoi Petru
Date: 2022.02.18 10:34:35 EET
Reason: MoldSign Signature
Location: Moldova

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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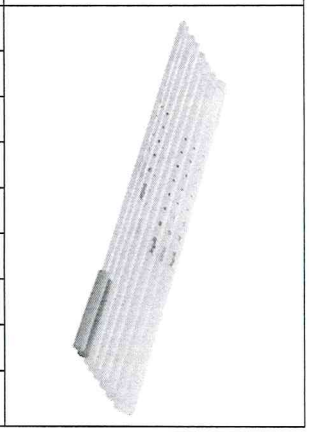
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

EC DECLARATION OF CONFORMITY

Manufacturer : Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.
1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey
Phone: +90 232 2816003 Fax: +90 232 2816648

Products :

Brand	Barcode	Ref	Product Name	Product Picture
MEDBAR	8698881910734	208 03	Karman Cannula No:3	
MEDBAR	8698881910147	208 04	Karman Cannula No:4	
MEDBAR	8698881910154	208 05	Karman Cannula No:5	
MEDBAR	8698881910161	208 06	Karman Cannula No:6	
MEDBAR	8698881910178	208 07	Karman Cannula No:7	
MEDBAR	8698881910185	208 08	Karman Cannula No:8	
MEDBAR	8698881910192	208 09	Karman Cannula No:9	
MEDBAR	8698881910208	208 10	Karman Cannula No:10	
MEDBAR	8698881910215	208 12	Karman Cannula No:12	

Intended Use : Incomplete abortion, first trimester abortion and / or menstruation regulation, as well as intrautherine cannulas intended for use with manual, syringe-like medical aspiration devices for aspirating fluid from the uterus by vacuum aspiration method and for abortion. They can be used for endometrium biopsy.

GMDN Code : 32655 – Intrauterine cannula, single-use
Classification : Class IIa
Classification Route : Annex V
Classification Rule : Rule 5

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and relative Medical Device Regulations. All supporting documentation is retained under the premises of the manufacturer.
We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Standards :

EN 556-1/AC	EN ISO 15223-1	EN ISO 20417	EN ISO 13485:2016/A11
TS EN 1895	TS 6074	EN ISO 14644-1, 2, 3, 4, 5	EN ISO 11135:2014+A1
EN ISO 11138-1, 2	EN ISO 11140-1	EN ISO 11607-1, 2	EN ISO 11737-1, 2
EN 62366-1	EN 868-5	EN ISO 14971:2019/A11	EN 1779/A1
ISO 11138-7	ISO 2859-1/Amd.1	ASTM F 88, 1886, 1929, 1980	EN ISO 10993-1,5,10, 18 EN ISO 10993-7:2008/AC

Notified Body Information : Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- Istanbul-Turkey
Certification No : 1984-MDD-20-682
Certification Date : 13.07.2020
Issue Place : Izmir/ Turkey
Issue Date : 29.09.2022
Signature : Hülya Urbay
(Quality Management Rep.)

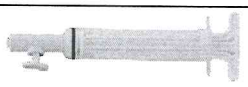
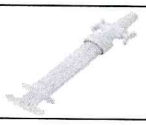
medbar®
TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.
Fatih Mah. 1142 Sokak No:35 Sarnıç - Gaziemir - İZMİR
Tel:0232 281 60 03 - 0232 281 66 47 Fax:0232 281 66 48
Mersis No:0613089864800025 Gaziemir V.D.513 089 8648

TD.07-UB.01(Rev3-29.09.2022)EN

EC DECLARATION OF CONFORMITY

Manufacturer : Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.
1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey
Phone: +90 232 2816003 Fax: +90 232 2816648

Products :

Brand	Barcode	Ref	Product Name	Product Picture
MEDBAR	8698881910222	209 01	Karman Single Valve Manual Vacuum Aspirator Set	
MEDBAR	8698881910239	209 02	Sterile Karman Double Valve Manual Vacuum Aspirator Set	
MEDBAR	8698881911366	209 04	Karman Single Valve Manual Vacuum Aspirator	
MEDBAR	8698881910819	209 05	Sterile Karman Double Valve Manual Vacuum Aspirator	

Intended Use : Incomplete abortion, first trimester abortion and / or menstruation arrangement, as well as manual, syringe-like medical aspiration devices intended to be used with the intrauterine cannula for aspirating fluid from the uterus and for abortion. They can be used for endometrium biopsy.

GMDN Code : 55840– Abortion suction system vacuum

Classification : Class II a

Classification Route : Annex V

Classification Rule : Rule 2

We hereby declare that above mentioned products meet the provisions of the latest version of European Medical Device Directive 93/42/EEC and relative Medical Device Regulations. All supporting documentation is retained under the premises of the manufacturer.

We declare that the products do not incorporate a substance of a human blood derivative, animal originated tissues, phthalates, medicinal product, latex, radioactive material and electromagnetic waves.

Standartlar :

EN 556-1/AC	EN ISO 15223-1	EN ISO 20417	EN ISO 13485:2016/A11
TS 7557	TS7558/T1	EN ISO 14644-1, 2, 3, 4, 5	EN ISO 11135:2014+A1
EN ISO 11138-1, 2	EN ISO 11140-1	EN ISO 11607-1, 2	EN ISO 11737-1, 2
ISO 11138-7	EN 868-5	EN ISO 14971:2019/A11	EN 1779/A1
ASTM F 88, 1886, 1929, 1980	ISO 2859-1/Amd.1	EN 1895:2001/AC	EN 62366-1
EN ISO 10993-1,5,10, 18	EN ISO 10993-7:2008/AC		

Notified Body Information : Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- Istanbul-Turkey

Certification No : 1984-MDD-20-682

Certification Date : 13.07.2020

Issue Place : Izmir/ Turkey

Issue Date : 29.09.2022

Signature : Hülya Urbay
(Quality Management Representative)

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