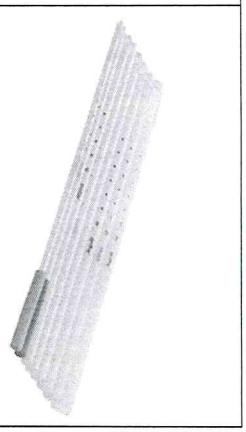
EC DECLARATION OF CONFORMITY

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.)

Digitally signed by Iarovoi Petru
Date: 2025.04.23 15:50:39 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

medbar®
TIBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.
Fatih Mah. 1142 Sokak No:35 Sarnıç - Gaziemir - İZMİR
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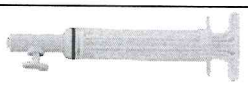
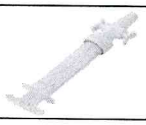
Mersis No:0613089864800025 Gaziemir V.D.513 089 8648

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

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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	8698881911335	273 01	Spirometer Filtered Mouthpiece (33 mm) (Small)	
MEDBAR	8698881911014	273 02	Spirometer Filtered Mouthpiece (30 mm) (Small)	
MEDBAR	8698881911601	273 03	Spirometer Filtered Mouthpiece with Nose Clip (33 mm) (Small)	
MEDBAR	8698881911618	273 04	Spirometer Filtered Mouthpiece with Nose Clip (30 mm) (Small)	
MEDBAR	8698881911793	273 05	Spirometer Filtered Mouthpiece (26 mm) (Small)	
MEDBAR	8698881911809	273 06	Spirometer Filtered Mouthpiece with Nose Clip (26 mm) (Small)	
MEDBAR	8698881911816	273 07	Spirometer Filtered Mouthpiece with Nose Clip (33 mm) (Large)	
MEDBAR	8698881911823	273 08	Spirometer Filtered Mouthpiece with Nose Clip (30 mm) (Large)	
MEDBAR	8698881912493	273 09	Spirometer Filtered Mouthpiece (33 mm) (Large)	
MEDBAR	8698881912509	273 10	Spirometer Filtered Mouthpiece (30mm) (Large)	

Intended Use : Medical device that provides a comfortable blowing by attaching to the inlet of the device during the Pulmonary Function test and prevents contamination of the main device and cross-contamination from the patient to the patient thanks to the filter inside. Nose Latch is the accompanying accessory used to increase the efficiency of the test during product testing. The nose clip is not a medical device.

GMDN Code : 61097– Pulmonary function testing filter/mouthpiece

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.

Standartlar :

TS EN ISO 14971	TS EN ISO 15223-1	TS EN 1041+A1	TS EN ISO 13485/AC
TS EN ISO 10993-1, 5, 10, 18		TS ISO 2859-1/A1	TS EN 62366-1

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 Place : 13.07.2020

Signature : Armağan Yalgın
(Quality Management Rep.)

TİBBİ MALZEMELER TUR. SAN. VE TİC. A.Ş.

TD.10-UB.01 (Rev3-13.07.2020)EN

CERTIFICATE

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

FATİH MAH. 1142 SOK. NO: 35 SARNIÇ GAZİEMİR - İZMİR - TURKEY

SURGICAL COVERS AND DRAPES PRODUCTS, IV FLOW REGULATOR PRODUCTS, KARMAN CANNULA PRODUCTS, ENDOSCOPY MOUTHPIECE PRODUCTS, MUCUS ASPIRATION COLLECTION CONTAINER PRODUCTS, VALVE URINE BAG PRODUCTS, ARTROCOPY SETS PRODUCTS, VALVE EMESIS BAG PRODUCTS, SURGICAL HAND BRUSHES, FILTERED MOUTHPIECE PRODUCTS, SMEAR BRUSHES, AMNIOTIC POUCH PERFORATOR, PARACON TUBE, SKIN MARKING SET, UMBILICAL CORD CLAMP, ARTERIAL CANNULA, EXTENSION LINE, ENDOMETRIAL SUCTION CURETTE, PHOTOTHERAPY EYE BAND (Y-BAND) PRODUCTS, STERILE LUER CONNECTOR CAP (STOPPER) PRODUCTION, PACKAGING OF INTENSIVE CARE PRODUCTS, STERILIZATION, STORAGE, DISTRIBUTION AND COMPLY WITH EN ISO 11135 STANDARD ETHYLENE OXIDE ACCORDING TO THE STANDARD OF ETHYLENE OXIDE STERILIZATION SERVICES STERILIZATION SERVICES

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2"

Certificate No	: M 11326
Initial Certification Date	: 03 October 2019
Certification Date	: 15 November 2022
Expiration Date	: 14 November 2025

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

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www.kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK BDS NO YS-92F5-54DF

Last Modified: 15 November 2022 - R 02