

MEDBAR TIBBİ MALZEMELER TURİZM SANAYİ VE TİCARET ANONİM ŞİRKETİ

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

SURGICAL DRAPE PRODUCTS, IV FLOW REGULATOR PRODUCTS, KARMAN CANNULA PRODUCTS, ENDOSCOPY MOUTHPIECES, MUCOUS ASPIRATION PRODUCTS, URINE COLLECTION PRODUCTS, ARTROCOPY SETS, VOMIT/EMESIS BAG PRODUCTS, SCRUB HAND BRUSHES, FILTERED MOUTHPIECE PRODUCTS, CERVICAL BRUSH PRODUCTS, AMNIOTIC POUCH PERFORATORS, FECAL PARASITE CONCENTRATION PRODUCTS, PHOTOTHERAPY EYE BAND (Y-BAND), ARTERIAL CANNULA, SKIN MARKING SET, UMBILICAL CORD CLAMP, ENDOMETRIAL SUCTION CURETTE, EXTENSION LINE, STERILE LUER CONNECTOR CAP (STOPPER) AND INTENSIVE CARE PRODUCTS PROCESSES: PRODUCTION, PACKAGING, STERILIZATION, STORING DISTRIBUTION AND ETHYLENE OXIDE STERILIZATION SERVICES ARE UNDER THE SCOPE OF EN ISO 11135 STANDARD

with a scope of

EN ISO 13485:2016

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

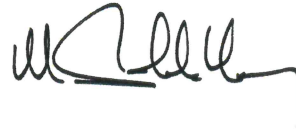
"Following elements of the standard are excluded"

"7.5.3" "7.5.4" "7.5.9.2"

Certificate No	: M 11326
Initial Certification Date	: 03 October 2019
Certification Date	: 03 October 2019
Expiration Date	: 02 October 2022

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

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General Manager



TÜRKAK BDS NO
YS-16BC-C2DD

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



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

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

Muhtesem Gökhan Yücel
Head of Notified Body

11 May 2021, Istanbul, Turkey

EC DECLARATION OF CONFORMITY

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

Products	Brand	Ref	Product Name
	MEDBAR	205 02	%7.5 Povidone Iodine Impregnated Hand Brush

Classification : Biocidal Type 1: Human hygiene

Active Materials : %7.5 Povidone Iodine (CAS No: 25655-41-8)

We declare that the product(s) mentioned above meet the requirements of the latest Biocidal Product Regulation published by the Ministry of Health of the Republic of Turkey. Necessary technical documents are available at the manufacturer. The product is not classified as a medical device.

Quantity : 20 ml

Appearance : Disinfectant impregnated brush

Shelf Life : 2 years

Target Organisms : E.coli, S.aureus, P.aeruginosa, C.albicans, E.hirae

Authority : Ministry of Health of The Republic of Turkey – Biocidal Directive

Licence Number : 2011/753

Place and Date : İzmir/ Turkey – 08.03.2019

Signature : Armağan Yalgın
(Biocidal Manager)

medbar
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Ticaret Sicil No: 067307914000013 Gaziemir V.D. 613 089 8640





EC DECLARATION OF CONFORMITY

Manufacturer Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.

Manufacturer Address 1142 sok. No:35 Fatih Mah. Sarnıç - İzmir / Turkey
Phone: +90 232 2816003 Fax: +90 232 2816648

SRN N/A

Brand	Barcode	Ref	Product Name	Product Photo
MEDBAR	8698881910390	228 01	Valve Emesis Bag Transparent	
MEDBAR	8698881911786	228 03	Valve Emesis Bag White	

Product Name

Intended Use

Medical devices with measurement function that are used to collect vomit and / or measure the vomit done by the patient in a certain time period in milliliters.

Basic UDI-DI

8698881910390LL

8698881911786MQ

Classification / Classification Rule

Class I m / Rule 1

Classification Route

Annex-IV (Annex II & III)

GMDN

36258 – Emesis bag

EMDN

N/A

Notified Body Information CE Certification Number and Date Regulations and Standards

Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- İstanbul-Turkey

1984-MDD-20-682 / 13.07.2020 – 27.05.2024

TS EN ISO 14971/D1	TS EN ISO 15223-1	TS EN 1041+A1	TS EN ISO 13485/AC
TS EN ISO 10993-1	TS EN 62366-1	TS ISO 2859-1/A1	TS EN ISO 80000-1

TD.16-UB.01(Rev0-15.10.2021)EN



As Medbar company, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation for these devices are fulfilled.

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.

Issue Place and Date : İzmir/Turkey 15.10.2021
Signature : Tuba SARI SAĞLAM
Title : Quality Management Representative

medbar®
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TD.16-UB.01(Rev0-15.10.2021)EN





EC DECLARATION OF CONFORMITY

- Manufacturer** : Medbar Tıbbi Malzemeler Turizm San. ve Ticaret A.Ş.
1142 sok. No:35 Fatih Mah. Sarnıç - İzmir / Turkey
Phone: +90 232 2816003 Fax: +90 232 2816648
- Intended Use** : Camera covers are sterile medical devices used to keep the environment sterile by covering the video camera cable or probe in cases where operations will be performed with a video camera in a sterile environment in hospitals.
- GMDN Code** : 37450 - Camera cover, single-use
- Classification** : Class I sterile
- Classification Route** : Annex V
- Classification Rule** : Rule 1

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	TS EN 13795-1	TS EN ISO 15223-1	TS EN 1041	TS EN ISO 13485/AC
	ASTM F 88, 1886, 1929, 1980	TS EN ISO 10993-1, 4, 5, 7, 10, 11,18	TS EN ISO 14644-1, 2, 3, 4, 5	TS EN ISO 11135 TS EN 62366-1
	TS EN ISO 11138-1, 2	TS EN ISO 11140-1	TS EN ISO 11607-1, 2	TS EN ISO 11737-1, 2
	TS EN ISO 22610	TS EN 868-5	TS EN ISO 14971/D1	TS EN 1779/A1
	TS EN ISO 14161	TS EN ISO 80369-7	TS EN 1895	

- Notified Body Information** : Kiwa Certification Services A.Ş. (NB 1984)
İTOSB 9. Cad No.15 Tepeören Tuzla- İstanbul-Turkey
- Certification No** : 1984-MDD-20-682
- Certification Date** : 13.07.2020
- Issue Place** : İzmir/ Turkey
- Issue Place** : 13.07.2020
- Signature** : Armağan Yalçın
(Quality Management Rep.)



Products:

Brand	Barcode	Ref	Product Name
MEDBAR	8698881910024	202 01	Cardboard Camera Cover 14x250cm
MEDBAR	8698881913117	202 15	Cardboard Camera Cover 14x140 cm
MEDBAR	8698881913933	202 27	Cardboard Camera Cover 18x300 cm
MEDBAR	8698881913162	202 25	Cardboard Camera Cover 14x300 cm
MEDBAR	8698881911922	202 05	Cardboard Camera Cover with Double Clips 14x250cm
MEDBAR	8698881912851	202 10	Cardboard Camera Cover 15x250
MEDBAR	8698881913124	202 16	Cardboard Camera Cover 15x300 cm
MEDBAR	8698881913131	202 17	Cardboard Camera Cover 18x250cm
MEDBAR	8698881912417	202 07	Cardboard Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881912936	202 28	Cardboard Camera Cover with Elastic Tip 14x140 cm
MEDBAR	8698881912943	202 29	Cardboard Camera Cover with Elastic Tip 15x300cm
MEDBAR	8698881912950	202 37	Cardboard Camera Cover with Elastic Tip 14x300cm





MEDBAR	8698881912981	202 30	Cardboard Camera Cover with Elastic Tip 18x300cm
MEDBAR	8698881912967	202 19	Cardboard Camera Cover with Elastic Tip 15x250 cm
MEDBAR	8698881912974	202 20	Cardboard Camera Cover with Elastic Tip 18x250 cm
MEDBAR	8698881914848	202-07WE	Cardboard Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881914855	202-37WE	Cardboard Camera Cover with Elastic Tip 14x300cm
MEDBAR	8698881914862	202-20WE	Cardboard Camera Cover with Elastic Tip 18x250cm
MEDBAR	8698881914879	202-30WE	Cardboard Camera Cover with Elastic Tip 18x300cm
MEDBAR	8698881914251	202 38	Cardboard Camera Cover 14x250 cm 100 micron Reverse Tipped
MEDBAR	8698881914268	202 39	Cardboard Camera Cover 18x250 cm 100 micron Reverse Tipped
MEDBAR	8698881914565	202 41	Cardboard Camera Cover 14x250cm Closed System with Lens
MEDBAR	8698881914800	202 43	Cardboard Camera Cover 18x250cm Closed System with Lens
MEDBAR	8698881914770	202 OGPC	Circled Ring Camera Cover Closed System 15x250cm (OptiGuard Pro Coupler)
MEDBAR	8698881914763	202 OGPA	Circled Ring Camera Cover Closed System Advanced 15x250 cm (OptiGuard Pro ArthrO)
MEDBAR	8698881914794	202 17 OGPC	Cardboard Camera Cover Closed System 18x250 cm (OptiGuard Pro Coupler) Promecon
MEDBAR	8698881914787	202 17 OGPA	Cardboard Camera Cover Closed System 18x250 cm (OptiGuard Pro ArthrO) Promecon
MEDBAR	8698881912899	202 03	Camera Cover Delta Teleskopik (Sterile)
MEDBAR	8698881912271	202 06	Telescopic Camera Cover 14x250 cm
MEDBAR	8698881913148	202 23	Telescopic Camera Cover 14x300 cm
MEDBAR	8698881913155	202 24	Telescopic Camera Cover 14x140 cm
MEDBAR	8698881913179	202 11	Telescopic Camera Cover 15x250 cm
MEDBAR	8698881913186	202 12	Telescopic Camera Cover 15x300 cm
MEDBAR	8698881913193	202 13	Telescopic Camera Cover 18x250 cm
MEDBAR	8698881913209	202 14	Telescopic Camera Cover 18x300 cm
MEDBAR	8698881913230	202 32	Telescopic Camera Cover with Elastic Tip 14x140 cm
MEDBAR	8698881913247	202 33	Telescopic Camera Cover with Elastic Tip 14x250 cm
MEDBAR	8698881913254	202 34	Telescopic Camera Cover with Elastic Tip 14x300 cm
MEDBAR	8698881913032	202 35	Telescopic Camera Cover with Elastic Tip 18x250 cm
MEDBAR	8698881913261	202 36	Telescopic Camera Cover with Elastic Tip 18x300 cm
MEDBAR	8698881914749	202-33WE	Telescopic Camera Cover 14x250 cm White Elastic Tip
MEDBAR	8698881914824	202-34WE	Telescopic Camera Cover 14x300 cm White Elastic Tip
MEDBAR	8698881914756	202-35WE	Telescopic Camera Cover 18x250 cm White Elastic Tip
MEDBAR	8698881914831	202-36WE	Telescopic Camera Cover 18x300 cm White Elastic Tip
MEDBAR	8698881913216	202 21	Accordion Folded Camera Cover 14x250 cm
MEDBAR	8698881913223	202 22	Accordion Folded Camera Cover 14x300 cm
MEDBAR	8698881912684	202 09	Circled Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881912998	202 31	Circled Camera Cover with Elastic Tip 15x250cm
MEDBAR	8698881914886	202-09WE	Circled Camera Cover with Elastic Tip 14x250cm
MEDBAR	8698881911045	202 02	Circled Camera Cover 14x250cm
MEDBAR	8698881914619	202 42	Circled Camera Cover with Perforated Tip
MEDBAR	8698881914817	202 44	Circled Camera Cover 15x250cm Closed System with Lens

TD.02-UB.02(Rev2-13.07.2020)EN



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

35+ yıllık deneyimimiz ile hep daha iyisi için çalışıyoruz...



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1142 sok. No:35 Fatih Mah. Sarnıç - İzmir / Turkey
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Products	Brand	Barcode	Ref	Product Name	Product Photo
	MEDBAR	8698881910857	229 01	Mucous Collection Container (40 ml)	
	MEDBAR	8698881911311	229 02	Mucous Collection Container (25 ml)	
	MEDBAR	8698881911533	229 03	Mucous Collection Container (100 ml)	
	MEDBAR	8698881912431	229 04	Mucous Collection Container (15 ml)	
	MEDBAR	8698881912905	305 01	Mucous Collection Container with Hose (40 ml)	

Intended Use : The sterile medical devices used to collect mucus drawn between the aspirator device used to collect mucus from the upper respiratory tract and nasal catheter in the diagnosis and treatment of respiratory diseases.

GMDN Code : 43947- Mechanical positive pressure airway secretion-clearing device

Classification : Class IIa

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.

Standards	TS EN 556-1	TS EN ISO 15223-1	TS EN 1041	TS EN ISO 13485/AC
	ASTM F 88, 1886, 1929, 1980		TS EN 1779/A1	TS EN ISO 11135
	TS EN ISO 11138-1, 2	TS EN ISO 11140-1	TS EN ISO 11607-1, 2	TS EN ISO 11737-1, 2
	TS EN ISO 1135-4	TS EN 868-5	TS EN ISO 14971/D1	TS EN 1895
	TS EN ISO 14161	TS ISO 2859-1/A1	TS EN ISO 14644-1, 2, 3, 4, 5	
	TS EN ISO 10993-1, 4, 5, 7, 10, 11,18		TS EN 62366-1	

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

Certification No : 1984-MDD-20-682

Certification Date : 13.07.2020

Issue Place : İzmir/ Turkey

Issue Place : 13.07.2020

Signature : Armağan Yalçın

(Quality Management Rep.)

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