CERTIFICATE

Digitally signed by Bolea Petru
Date: 2022.03.14 09:51:45 EET
Reason: MoldSign Signature
Location: Moldova

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

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

General Manager

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-16BC-C2DD

Last Modified: 11 May 2021 - R 01

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.
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

DECLARATION OF CONFORMITY

Manufacturer	:	Medbar Tıbbi Malzemeler Turizm San. ve Tic. A.Ş. 1142 sok. No:35 Fatih Mah. Sarnıç - Izmir / Turkey Phone: +90 232 2816003 Fax: +90 232 2816648
Product(s)	:	Single Use Surgical Hand Brush Impregnated with % 4 Chlorhexidine
Classification	:	Biocide Type 1: Biocidal products for human hygiene purposes.

We hereby declare that above mentioned products meet the provisions of the latest version of The Biocidal Product Directive. All supporting documentation is retained under the premises of the manufacturer.

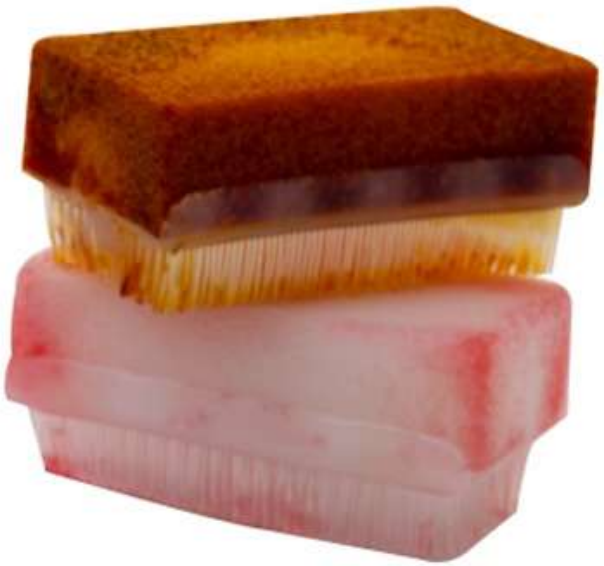
Active Substance(s)	:	Chlorehexidine gluconate (CAS No: 18472-51-0)
Amount	:	20 ml
Appearance	:	Brush impregnated with disinfectant
Shelf Life	:	2 years
Target Organism(s)	:	*Staphylococcus aureus, Escheriachia coli, Pseudomonas aeruginosa, Candida albicans.*
Competent Authority	:	Ministery of Health of the Republic of Turkey
License No	:	2011/754
Place, Date of Issue	:	Izmir/ Turkey – 12.02.2018
Signature	:	

Ü.Ömer Baran
(General Manager)

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: 0613091400013 Gaziemir VD. 613 089 8648

medbar®

Impregnated Hand Brushes



REF 205

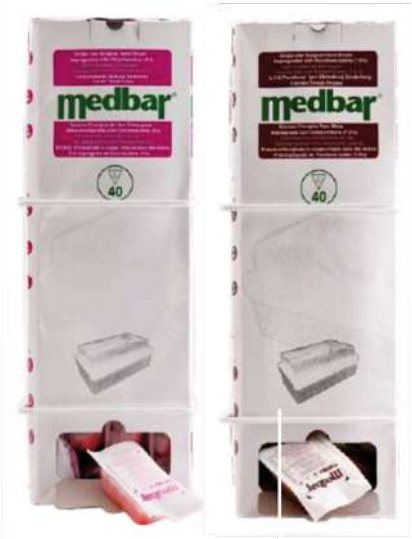
STERILE EO

BIOCIDAL

Impregnated Hand Brushes

Intended Use

- Used to clean hands before surgeries.



Components of The Product

Medbar brand Impregnated Hand Brushes consist of :

- Brush,
- Sponge,
- Biocidal.

Product Features

- Ergonomic brush design (48*79*34 mm).
- Easy open package.
- Soft bristles to avoid skin irritation.
- With or Without nail prick.
- Smooth and soft sponge absorbs up to 90 ml liquid.
- Chlorhexidine Gloconate and Povidine-Iodine options.
- For external use only.

Quality

- Biocidal Licensed.(Impregnated).
- Manufactured under ISO 13485:2012 Quality Management System standard.

Sterilization

- Non-sterile.

Shelf Life

- 2 years.

Biocompability

- Latex-free.

REF NO	PRODUCT NAME	STERILIZATION	PACKAGING
205 01	Single Use Surgical Hand Brush 4% Chlorhexidine	-	40 pcs inner box/400 pcs outer box
205 02	Single Use Surgical Hand Brush 7.5% Povidine-Iodine	-	Box Dimensions: 67*35*54 cm

Medbar Tıbbi Malzemeler Turizm San. Tic. A.Ş.
1142 Sk. No:35 Sarnıç Gaziemir-İzmir/Turkey
T: +90 232 2816003 - F: +90 232 2816648
www.medbar.com.tr - info@medbar.com.tr

T.C. Sağlık Bakanlığı
Türkiye Halk Sağlığı Kurumu

T.C.
SAĞLIK BAKANLIĞI
Türkiye Halk Sağlığı Kurumu

BİYOSİDAL ÜRÜN RUHSATNAMESİ

(İMALÂT)

Ruhsat No	2011/ 754	Ruhsat Tarihi	16.12. 2011
Ürünün Ticari Adı/Tipi	% 4 KLORHEKSİDİN GLUKONAT EMDİRİLMİŞ CERRAHİ TIRNAK FIRÇASI /1		
Aktif Madde/ler İsimleri	Klorheksidin Glukonat.		
Aktif Madde/ler CAS numaraları	18472-51-0.		
Aktif Madde/ler ve Oranları	Klorheksidin Glukonat % 4.		
Hedef canlı/canlılar	*Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans.*		
Fiziki Hali (Toz, Briket, Granül vb.)	Klorheksidin Glukonat emdirilmiş tırnak fırçası.		
Uygulama dozu	Kullanıma hazır.		
Ambalaj miktarı/ları	20 ml.		
Antidotu	Spesifik bir antidotu yoktur.		
Risk ve Güvenlik İbareleri	S2, S25, S46.		
Raf ömrü	2 (iki) yıl		
Ruhsat Sahibinin Adı ve Adresi	MEDBAR TIBBİ MALZEMELER TURİZM SAN. VE TİC. LTD. ŞTİ. 142/2 Sok. No:3 Sarnıç Gaziemir/İZMİR		
Fabrika veya İmalathanenin Adresi	MEDBAR TIBBİ MALZEMELER TURİZM SAN. VE TİC. LTD. ŞTİ. 142/2 Sok. No:3 Sarnıç Gaziemir/İZMİR		
Ruhsatın Geçerli Olduğu Süre	31/12/2015		
Veriliş Tarihi ve Sebebi	08/12/2014 Yenileme (Süre uzatımı kapsamında)		

31.12.2009 tarihli ve 27449 sayılı 4'üncü mükerrer Resmî Gazete'de yayımlanan Biyosidal Ürünler Yönetmeliğinin 14 üncü maddesi uyarınca yukarıda adı geçen biyosidal ürünün imaline ve kullanılmasına müsaade edilmiştir.

Dr. Hüseyin İLTER
Daire Başkanı

31.12.2015 tarihli ve E. 9819 sayılı
olur gereği ruhsat süresi 31.08.2016
tarihine kadar uzatılmıştır.

Uzm. Dr. Hasan IRMAK
Kurum Başkanı a.
Başkan Yardımcısı

Not: 24 Aylık stabilite testleri tamamlandığında uygun bulunması halinde ruhsat süresi uzatılacaktır.