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# CERTIFICATE

## Full Quality Assurance System

## Medical Devices Directive 93/42/EEC Annex II

Company Name : Medbar Tıbbi Malzemeler Turizm San ve Tic. A.Ş.

Company Address : 1142 Sokak No:35 Sarnıç Gaziemir IZMIR / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)

Product :
- Phototherapy Eye Band - Class Is
- Endoscopy Mouthpiece - Class Is
- Pouch Perforator - Class Is
- Cervix Brush - Class Is
- Cervical Brush - Class Is
- Smear Spatula - Class Is
- Limb Holder - Class Is
- Tracheostomy Fixer - Class Is
- Endotracheal Tube Fixer - Class Is
- Endometrial Suction Curette - Class Is
- Insemination Cannula - Class Is
- Surgical Drapes, Covers and Gowns - Class Is
- Cardboard Camera Cover - Class Is
- Circled Camera Cover - Class Is
- Microscope Drape - Class Is
- Video Camera Cover - Class Is
- Umblical Cord Clamp - Class Is
- Valve Urine Bag - Class Im
- Valve Emesis Bag - Class Im
- Gastric Lavage Set - Class Im
- Karman Cannula Injector (Manuel Vacuum Aspirator)- Class IIa
- Karman Cannula - Class IIa
- Arthroscopy Set - Class IIa
- Mucous Aspirator - Class IIa
- IV Flow Controller (Controflow)- Class IIa
- Skin Marking Set - Class IIa
- Spirometer Filtered Mouthpiece - Class IIa
- Arterial Cannula - Class IIa

Certificate Number : M.2016.106.7000

Report Number : MD.3184.IB

Initial Assessment Date : 01.07.2016

Registration Date : 03.10.2016

Revision Date /No : -

Expiry Date : 02.10.2021

UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through www.udemltd.com. tr.

CE 2292

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Mentioned company is a member of "Ankara Chamber of Commerce"
with the registration number .....
"Ankara Chamber of Commerce" is not responsible for the content of this
document (agreement/insurance policy/declaration etc.) and will not take
any responsibility in case of a disagreement.

*T.C.*

09 AUG 2017

Songül HAVA
Foreign Trade Department