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CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Medbar Tıbbi Malzemeler Turizm San ve Tic. A.Ş.
Company Address	: 1142 Sokak No:35 Sarnıç Gaziemir İZMİR / TURKEY
Related Directives and Annex	: 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 Tracheostomy Fixer - Class Is Endotracheal Tube Fixer - Class Is Hand Fixer - Class Is Foot Fixer - Class Is Hand and Foot Fixer Child/Baby - Class Is Endometrial Suction Curette - Class Is Microscope Drape - Class Is Video Camera Cover - Class Is Circled Camera Cover - Class Is Cardboard Camera Cover - Class Is Endoseal Bag - Class Is Scopy/Flouroscopy Drape - Class Is Light Handle 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
GMDN	: 45189, 10405, 12990, 32368, 32679, 35752, 35815, 12102, 12094, 12097, 32655, 12535, 37450, 43970, 44977, 43998, 58918, 36258, 58985, 62162, 32655, 36003, 43947, 35894, 61575, 61097, 34893
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	: 24.02.2020/01
Expiry Date	: 02.10.2021

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

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applied 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. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. 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 validity of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

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