CERTIFICATE

Full Quality Assurance System

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

M.2016.106.6949-1 Desingn Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Betatech Medikal Cihazlar Sanayi Mümessillik İç ve Dış Ticaret Ltd. Şti.
Company Address	: İkitelli Org. San. Blg. Atatürk Oto San. Sit. Ünal İş Merkezi 22. Sk. No:9 Başakşehir İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Sterile Neurosurgical Patty - Class III - Radiopaque, with thread - Radiopaque, without thread Sterile Partially Absorbable Composite Mesh - Class III - Polymesh Composite - Polymesh Inova Sterile Absorbable Hemostat Oxidized Regenerated Cellulose - Class III Sterile Dual Side Surgical Mesh - Class IIb Sterile Surgical Mesh for Hernia and Pelvic Surgery - Class IIb Sterile Adhesion Barrier Gel - Class III
GMDN	: 13702, 34212, 47986, 60300, 44756, 58298
Certificate Number	: M.2016.106.6949
Report Number	: MD.3135.YB
Initial Assessment Date	: 20.05.2016
Registration Date	: 25.08.2016
Recertification Assessment Date	: 21.08.2019
Reissue Date / No	: 04.06.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

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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