CERTIFICATE

Full Quality Assurance System

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

Company Name	: Düzey Medikal Cihazlar Sanayi Ticaret Limited Şirketi
Company Address	: İçmeler Mah. Özyaman Sokak No:23/A Tuzla İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile Surgical Polypropylene Mesh - Class IIb - Sterile Vaginal Tape For Incontinance - Class IIb - Vaginal Tape Cystocele - Vaginal Tape Rectocele - Vaginal Tape Mini Siling - Vaginal Tape Mini Siling Set - Vaginal Tape Suprapubic Set - Vaginal Tape Transopturator Set - Vaginal Tape Helical Set
GMDN	: 60300, 47986
Certificate Number	: M.2016.106.7121
Report Number	: MD.3189.YB
Initial Assessment Date	: 29.07.2016
Registration Date	: 11.11.2016
Recertification Assessment Date	: 06.09.2019
Reissue Date / No	: 05.02.2020/01
Revision Date /No	: -
Expiry Date	: 27.05.2024

APPROVED

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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