CERTIFICATE

Full Quality Assurance System

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

M.2016.106.6908-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: TMT Tıbbi Medikal Malzemeleri Sanayi ve Ticaret A.Ş.
Company Address	: Fatih Mah. 1188 Sok. No: 14 Sarnıç Gaziemir İZMİR / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: 1- Spinal Anesthesia Needles - Sets - Kits - Class III - Sterile - Spinal Anesthesia Needles - Spinal Anesthesia Sets - Combined Spinal Epidural Anesthesia Sets - Combined Spinal Epidural Anesthesia Kits 2- Epidural Anesthesia Needles - Sets - Kits - Class IIa - Sterile - Epidural Anesthesia Needles - Epidural Anesthesia Sets - Epidural Anesthesia Kits - Echogenic Transforaminal Epidural Cannula with Blunt Tip - Echogenic Transforaminal Epidural Cannula with Blunt Tip Sets - Caudal Anesthesia Needles - Caudal Anesthesia Sets 3- IIntrauterine Contraceptive Device - Class III - Sterile 4- Seldinger (Angiography) Needle - Class III - Sterile 5- Biopsy and Aspiration Needles-Kits and Accessories - Class IIa - Sterile 6- Medical Accessories for Anesthesia - Class IIa - Sterile 7- Medical Accessories for Anesthesia-Class I - Sterile
GMDN	: 35212, 34845, 58293, 34842, 45178, 34841, 46920, 12747, 47540, 35886, 46350, 45018, 45316, 31245, 18069, 35795, 34916, 37040, 46115 Product Types are attached.
Certificate Number	: M.2016.106.6908
Report Number	: MD.3193.YB
Initial Assessment Date	: 16.07.2016
Registration Date	: 28.07.2016
Recertification Assessment Date	: 01.08.2019
Reissue Date / No	: 20.01.2020/01
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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