Digitally signed by Granaci Boris
Date: 2021.02.25 14:58:34 EET
Reason: MoldSign Signature
Location: Moldova

E C C E R T I F I C A T E

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Dört A Tıp Malzemeleri San. İth. İhr. Tic. Ltd. Şti.
Company Address	: Balıkhisar Mah. Köyiçi Serpmeleri No:795/A Akyurt ANKARA / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Polypropylene mesh - Class IIb - Esu Pencil - Class IIb - PSS Drain (blue x-ray line) - Class IIa - T Drain - Class IIa - PVC Straight Drain (normal- blue x-ray line) - Class IIa - Silicone Straight Drain (normal- blue x-ray line) - Class IIa - Worth / Sump Drain (blue x-ray line) - Class IIa - PVC Thorax Drain (blue x-ray line) - Class IIa - Silicone Thorax Drain (blue x-ray line) - Class IIa - Flat Drain (normal/ blue x-ray line) - Class IIa - PVC Redon Drain (blue x-ray line) - Class IIa - Silicone Redon Drain (blue x-ay line) - Class IIa - Channel Drain (normal/ blue x-ray line) (Flat/ round) - Class IIa - Drain Suction Set (Yankuer Set) Vacuum/ Non- vacuum - Class IIa - Penrose Drain (blue x-ray line) - Class IIa - Silicone Hemovac Drain Set Single/ Double - Class IIa - PVC Hemovac Drain Set Single / Double - Class IIa - Esu Pencil Cleaner - Class Is - Aspiration Tube - Class Is - Passive Chest Drainage Bottle 2000ml - Class Is - Bomb Reservoir - Class Is
GMDN	: 44681, 60300, 35118, 35824, 11305, 11301, 35917, 44643
Certificate Number	: M.2016.106.7276
Report Number	: MD.3334.TR-011-YB
Initial Assessment Date	: 31.07.2012
Registration Date	: 05.12.2016
Recertification Assessment Date	: 26.07.2017
Reissue Date	: 24.10.2017/01
Revision Date /No	: -
Expiry Date	: 07.08.2022

APPROVED 2292

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

The certificate is not in force between 07.08.2017-24.10.2017.

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 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 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.udem.com. tr.

CE 2292

Addres: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr