EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

Company Name	: Morton Medikal San. ve Tic. A.Ş.
Company Address	: İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Tekeli Menderes IZMIR / TURKEY
Related Directives and Annex	: MDD 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-sterile Anesthesia and Breathing Circuit - Class IIa Sterile Bacterial Filter - Class IIa Sterile Catheter Mouth - Class IIa Sterile Mortonvent Tracheostomy Filter Set - Class IIa Non-sterile Spirometry Filter and Mouth Piece - Class IIa Sterile Inhalation Holding Chamber - Class IIa Non-sterile Humidifier Chamber - Class IIa Sterile Extension Line - Class IIa Sterile Pleural Drainage System - Class IIa Sterile Y Tur Set - Class IIa Sterile Yankauer Suction Set - Class IIa Non-Sterile Disposible Anesthesia Rebreathing Bag - Class IIa Sterile Video Camera Drape - Class Is Sterile Microscope Drape - Class Is
GMDN	: 37704, 37706, 37798, 37597, 35795, 37597, 13680, 60699, 12170, 16621, 10817, 46102, 35917, 37450, 12535, 34877
	Product Types are attached.
Certificate Number	: M.2017.106.8574
Report Number	: MD.3375.IB
Initial Assessment Date	: 30.05.2017
Registration Date	: 23.06.2017
Revision Date /No	: 18.08.2017/02
Expiry Date	: 22.06.2022

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

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 Co. Ltd. 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.udemltd.com. tr.

CE 2292

Addrres: 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.udemltd.com.tr