



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

Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name : Morton Medikal San. ve Tic. A.Ş.

Company Address : İTOB O.S.B. Ekrem Demirtaş Cad. No:9 Tekeli Menderes İZMİR / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex V

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 Disposable 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 : 24.09.2018/03

Expiry Date : 22.06.2022


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

UDEM hereby declares that the requirements of Annex V, 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 V, section 4 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.

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Address: 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

PRODUCT	CLASS	GMDN
NONSTERILE ANESTHESIA AND BREATHING CIRCUIT		
MN 100-01PV, MN 100-02PV, MN 100-03PV, MN 100-04PV, MN 100-05PV, MN 100-01PE, MN 100-02PE, MN 100-03PE, MN 100-04PE, MN 100-05PE, MN 100-06PV, MN 100-07PV, MN 100-08PV, MN 100-09PV, MN 100-10PV, MN 100-06PE, MN 100-07PE, MN 100-08PE, MN 100-09PE, MN 100-10PE, MN 100-11PV, MN 100-12PV, MN 100-13PV, MN 100-14PV, MN 100-15PV, MN 100-11PE, MN 100-12PE, MN 100-13PE, MN 100-14PE, MN 100-15PE, MN 100-16PV, MN 100-17PV, MN 100-18PV, MN 100-19PV, MN 100-20PV, MN 100-16PE, MN 100-17PE, MN 100-18PE, MN 100-19PE, MN 100-20PE, MN 101-01PV, MN 101-02PV, MN 101-03PV, MN 101-04PV, MN 101-05PV, MN 101-01PE, MN 101-02PE, MN 101-03PE, MN 101-04PE, MN 101-05PE, MN 101-06PV, MN 101-07PV, MN 101-08PV, MN 101-09PV, MN 101-10PV, MN 101-06PE, MN 101-07PE, MN 101-08PE, MN 101-09PE, MN 101-10PE, MN 101-11PV, MN 101-12PV, MN 101-13PV, MN 101-14PV, MN 101-15PV, MN 101-11PE, MN 101-12PE, MN 101-13PE, MN 101-14PE, MN 101-15PE, MN 101-16PV, MN 101-17PV, MN 101-18PV, MN 101-19PV, MN 101-20PV, MN 101-16PE, MN 101-17PE, MN 101-18PE, MN 101-19PE, MN 101-20PE, MN 102-01PV, MN 102-02PV, MN 102-03PV, MN 102-04PV, MN 102-05PV, MN 102-01PE, MN 102-02PE, MN 102-03PE, MN 102-04PE, MN 102-05PE, MN 102-06PV, MN 102-07PV, MN 102-08PV, MN 102-09PV, MN 102-10PV, MN 102-06PE, MN 102-07PE, MN 102-08PE, MN 102-09PE, MN 102-10PE, MN 102-11PV, MN 102-12PV, MN 102-13PV, MN 102-14PV, MN 102-15PV, MN 102-11PE, MN 102-12PE, MN 102-13PE, MN 102-14PE, MN 102-15PE, MN 102-16PV, MN 102-17PV, MN 102-18PV, MN 102-19PV, MN 102-20PV, MN 102-16PE, MN 102-17PE, MN 102-18PE, MN 102-19PE, MN 102-20PE, MN 103-01PV, MN 103-02PV, MN 103-03PV, MN 103-04PV, MN 103-05PV, MN 103-01PE, MN 103-02PE, MN 103-03PE, MN 103-04PE, MN 103-05PE, MN 103-06PV, MN 103-07PV, MN 103-08PV, MN 103-09PV, MN 103-10PV, MN 103-06PE, MN 103-07PE, MN 103-08PE, MN 103-09PE, MN 103-10PE, MN 103-11PV, MN 103-12PV, MN 103-13PV, MN 103-14PV, MN 103-15PV, MN 103-11PE, MN 103-12PE, MN 103-13PE, MN 103-14PE, MN 103-15PE, MN 103-16PV, MN 103-17PV, MN 103-18PV, MN 103-19PV, MN 103-20PV, MN 103-16PE, MN 103-17PE, MN 103-18PE, MN 103-19PE, MN 103-20PE, MN 104-01PV, MN 104-02PV, MN 104-03PV, MN 104-04PV, MN 104-05PV, MN 104-01PE, MN 104-02PE, MN 104-03PE, MN 104-04PE, MN 104-05PE, MN 104-06PV, MN 104-07PV, MN 104-08PV, MN 104-09PV, MN 104-10PV, MN 104-06PE, MN 104-07PE, MN 104-08PE, MN 104-09PE, MN 104-10PE, MN 104-11PV, MN 104-12PV, MN 104-13PV, MN 104-14PV, MN 104-15PV, MN 104-11PE, MN 104-12PE, MN 104-13PE, MN 104-14PE, MN 104-15PE, MN 104-16PV, MN 104-17PV, MN 104-18PV, MN 104-19PV, MN 104-20PV, MN 104-16PE, MN 104-17PE, MN 104-18PE, MN 104-19PE, MN 104-20PE, MN 105-01PV, MN 105-02PV, MN 105-03PV, MN 105-04PV, MN 105-05PV, MN 105-01PE, MN 105-02PE, MN 105-03PE, MN 105-04PE, MN 105-05PE, MN 105-06PV, MN 105-07PV, MN 105-08PV, MN 105-09PV, MN 105-10PV, MN 105-06PE, MN 105-07PE, MN 105-08PE, MN 105-09PE, MN 105-10PE, MN 105-11PV, MN 105-12PV, MN 105-13PV, MN 105-14PV, MN 105-15PV, MN 105-11PE, MN 105-12PE, MN 105-13PE, MN 105-14PE, MN 105-15PE, MN 105-16PV, MN 105-17PV, MN 105-18PV, MN 105-19PV, MN 105-20PV, MN 105-16PE, MN 105-17PE, MN 105-18PE, MN 105-19PE, MN 105-20PE, MN 106PE, MN 107PE, MN 108PE, MN 109PE, MN 110PE, MN 111PE, MN 112PE, MN 113PE, MN 114PE, MN 115PE, MN 116PE, MN 117PE, MN 118PE, MN 119PE, MN 120PE, MN 121PV, MN 148PE, MN 149PE, MN 150PE, MN 151PE, MN 152PE,	Class IIa	37704 37706

MN 153PE, MN 154-01PE, MN 154-02PE, MN 154-03PE, MN 154-04PE, MN 155-01PE, MN 155-02PE, MN 155-03PE, MN 155-04PE, MN 156PE, MN 157-01PE, MN 157-02PE, MN 157-03PE, MN 157-04PE, MN 158-01PE, MN 158-02PE, MN 159-03PE, MN 159-04PE, MN 160-01PE, MN 160-02PE, MN 160-03PE, MN 160-04PE, MN 161-01PE, N 161-02PE, MN 161-03PE, MN 161-04PE, MN 162-01PE, MN 162-02PE, MN 162-03PE, MN 162-04PE, MN 163-01PE, MN 163-02PE, MN 163-03PE, MN 163-04PE, MN 164-01PE, MN 164-02PE, MN 165-01PE, MN 165-02PE, MN 166-01PE, MN 166-02PE, MN 166-03PE, MN 166-04PE, MN 167-01PE, MN 167-02PE, MN 168-01PE, MN 168-02PE, MN 169-01PE, MN 169-02PE, MN 170-01PE, MN 170-02PE, MN 171-01PE, MN 171-02PE, MN 172-01PE, MN 172-02PE, MN 173-01PE, MN 173-02PE, MN 174-01PE, MN 174-02PE, MN 175-01PE, MN 175-02PE, MN 176-01PE, MN 176-02PE, MN 177-01PE, MN 177-02PE, MN 178-01PE, MN 178-02PE, MN 179-01PE, MN 179-02PE, MN 180-01PE, MN 180-02PE, MN 181-01PE, MN 181-02PE, MN 190PE, MN 191PE, MN 192PE, MN 193PE		
STERİLE BACTERIAL FILTER		
MN 136, MN 137, MN 137-01, MN 137-02	Class IIa	37798 37597
STERILE CATHETER MOUTH		
MN 132-01, MN 132-02, MN 132-03, MN 132-04, MN 132-05, MN 132-06, MN 132-07, MN 132-08	Class IIa	35795
STERILE MORTONVENT TRACHEOSTOMY FILTER SET		
MN 138-01, MN 138-02	Class IIa	37597
NONSTERILE SPIROMETRY FILTER AND MOUTH PIECE		
MN 910, MN 910-01, MN 910-02, MN 912	Class IIa	13680
STERILE INHALATION HOLDING CHAMBER		
MN 137-03	Class IIa	35530
NONSTERILE HUMIDIFIER CHAMBER		
MN 135-01, MN 135-02	Class IIa	60699
STERILE EXTENSION LINE		
MN 201, MN 204, MN 208	Class IIa	12170, 16621
STERILE PLEURAL DRAINAGE SYSTEM		
MN 400, MN 401	Class IIa	10817
STERILE Y TUR SET		
MN 300, MN 301	Class IIa	46102
STERILE YANKAUER SUCTION SET		
MN 302, MN 303, MN 304	Class IIa	35917
NON-STERILE DISPOSABLE ANESTHESIA REBREATHING BAG		
MN 124-01, MN 124-02, MN 124-03, MN 124-03	Class IIa	34877
STERILE VIDEO CAMERA DRAPE		
MN 900, MN 901	Class Is	37450
STERILE MICROSCOPE DRAPE		
MN 902, MN 903	Class Is	12535