



# 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](http://www.udem.com.tr).

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This document containing 2 (two) pages is the Annex of the Certificate with the revision number 03, with the number M.2017.106.8574 and with the registration date of 23.06.2017 and with the revision date of 24.09.2018 issued for "Morton Medikal San. ve Tic. A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

PRODUCT	CLASS	GMDN
<b>NONSTERILE ANESTHESIA AND BREATHING CIRCUIT</b>		
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



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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		
<b>STERILE BACTERIAL FILTER</b>		
MN 136, MN 137, MN 137-01, MN 137-02	Class IIa	37798 37597
<b>STERILE CATHETER MOUTH</b>		
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
<b>STERILE MORTONVENT TRACHEOSTOMY FILTER SET</b>		
MN 138-01, MN 138-02	Class IIa	37597
<b>NONSTERILE SPIROMETRY FILTER AND MOUTH PIECE</b>		
MN 910, MN 910-01, MN 910-02, MN 912	Class IIa	13680
<b>STERILE INHALATION HOLDING CHAMBER</b>		
MN 137-03	Class IIa	35530
<b>NONSTERILE HUMIDIFIER CHAMBER</b>		
MN 135-01, MN 135-02	Class IIa	60699
<b>STERILE EXTENSION LINE</b>		
MN 201, MN 204, MN 208	Class IIa	12170, 16621
<b>STERILE PLEURAL DRAINAGE SYSTEM</b>		
MN 400, MN 401	Class IIa	10817
<b>STERILE Y TUR SET</b>		
MN 300, MN 301	Class IIa	46102
<b>STERILE YANKAUER SUCTION SET</b>		
MN 302, MN 303, MN 304	Class IIa	35917
<b>NON-STERILE DISPOSABLE ANESTHESIA REBREATHING BAG</b>		
MN 124-01, MN 124-02, MN 124-03, MN 124-03	Class IIa	34877
<b>STERILE VIDEO CAMERA DRAPE</b>		
MN 900, MN 901	Class Is	37450
<b>STERILE MICROSCOPE DRAPE</b>		
MN 902, MN 903	Class Is	12535