BACTERIAL FILTERS

Filters are intended to be replaced at least once every 24 hours. Bacterial Filters are using with breathing circuits during anesthesia and ventilation operations to avoid risk of bacteria and viruses before they enter a patient's airway. Without them patient can be risk for infection.

MN 136 Bacterial Filter
Bakteri Filtresi

TECHNICAL PROPERTIES	
Tidal Volume(ml)	: 150-1500
Dead Space(ml)	: 33
Bacterial-Viral Efficiency	: >99,9999%
Viral Efficiency	: >99,999%
Resistance to Flow	: 30 lt/min 4,3 mm H_2O
	60 lt/min 12 mm H_2O
	90 lt/min 25 mm H_2O
Weight (gr)	: 19
Fittings (ISO Connectors)	: 22M-15/22MF
CO_2 sampling port	

MN 137 Bacterial HME Adult
Bakteri Filtresi, Nemli, Yetişkin

With foam

TECHNICAL PROPERTIES	
Tidal Volume(ml)	: 150-1500
Dead Space(ml)	: 53
Bacterial-Viral Efficiency	: >99,9999%
Viral Efficiency	: >99,999%
Resistance to Flow	: 30 lt/min 9,4 mm H_2O
	60 lt/min 23,2 mm H_2O
	90 lt/min 42 mm H_2O
Weight (gr)	: 30
Fittings (ISO Connectors)	: 22M - 15/22MF
Humidification Efficiency	: 36,8 mg/l H_2O (500ml tid. vol)
CO_2 sampling port	

With paper

MN 137 - 01 Bacterial Filter HME Pediatric
Bakteri Filtresi, Nemli, Pediatrik

TECHNICAL PROPERTIES	
Tidal Volume(ml)	: 150-300
Dead Space(ml)	: 12
Filtration Efficiency	: BFE 99,9999%; VFE 99,9999%
Humidification Efficiency	: 24 mg/l H_2O (500 ml. tid. vol.)
Resistance to Flow	: 30 lt/min 13 mm H_2O
Weight (gr)	: 13,5
Fittings (ISO Connectors)	: 22F-22M/15F
CO_2 sampling port	

MN 137 - 02 Bacterial Filter HME Infant
Bakteri Filtresi, Nemli, Yenidoğan

TECHNICAL PROPERTIES	
Tidal Volume(ml)	: 70-150
Dead Space(ml)	: 8
Filtration Efficiency	: BFE 99,9999%; VFE 99,9999%
Humidification Efficiency	: 24 mg/l H2O (500 ml. tid. vol.)
Resistance to Flow	: 30 lt/min 13 mm H_2O
Weight (gr)	: 8
Fittings (ISO Connectors)	: 15F-15M/8M
CO_2 sampling port	

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 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	: 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.

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

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
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

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Mutlukent Mahallesi 2073. Sokak (Eski 93 Sokak) No:10 Ümitköy – Çankaya – ANKARA
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UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

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.

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 166-01PE, MN 166-02PE, 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 DISPOSIBLE ANESTHESIA REBREATHINGBAG		
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

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

PCA
PARTNERS CERTIFICATE ASSURANCE

Certificate

ISO 13485 : 2016

MORTON MEDİKAL SAN. VE TİC. A.Ş.
İTOB OSB Mah. Ekrem Demirtaş Cad. No:9 Menderes İzmir / TURKEY

This certificate shows that the medical devices - quality management system (EN ISO 13485:2016) of the above company was approved by PCA Certification for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria

SCOPE

Manufacture and sales of disposable anesthesia, infusion, aspiration products and non-active instruments (Microscope case, camera case, kapkon connector)

GROUP CODE

A - D

Certificate No	: TC-75017
Registration Date	: 15.12.2017
Reissue Date	: 14.12.2021
Expiry Date	: 14.12.2022
Certificate Period	: 3 Years (From the date of registration)
Exclusion	: 7.3/7.5.3/7.5.4/7.5.9.2/7.5.10/8.3.4

IAS ACCREDITED
Management Systems Certification Body
MSCB-103

PCA Certification Approval

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