



CERTIFICATE

MEDİTERA TIBBİ MALZEME SAN. VE TİC. A.Ş.

HQ: 5758 SOKAK NO: 4/C-E KARABAĞLAR - İZMİR - TURKEY
FACTORY: İBNİMELEK OSB MH. TOSBİYOL 4 SK. NO:29 TİRE - İZMİR - TURKEY

DESIGN AND DEVELOPMENT, MANUFACTURE AND DISTRIBUTION OF BREATHING
AND INFUSION SYSTEMS AND SERVICE OF INFUSION DEVICES. STERILIZATION
FOR MEDICAL DEVICES ACCORDING TO REQUIREMENTS OF EN ISO 11135

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.3" "7.5.9..2"

Certificate No	: M 11573
Initial Certification Date	: 21 September 2018
Certification Date	: 16 September 2021
Expiration Date	: 15 September 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Certificate is valid till expiration date,
subject to successful completion of
periodical surveillance audits.
Please contact above numbers for
detailed information.

General Manager



TÜRKAK BDS NO
YS-2555-50AF

AT Sertifikası
Üretim Kalite Güvence Sistemi
Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-19-588

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

MEDİTERA TIBBİ MALZEME
SANAYİ VE TİCARET ANONİM ŞİRKETİ

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TÜRKİYE

Ürünler: Solunum Devreleri, Isıtıcı Telli Devre, Anestezi Balonu, Solunum Maskesi, Filtre, IV Set ve Konnektörler, Kateter Mount, Enjektör Kilit Adaptörü, Biyosidal Aparatı

Ürünler, sertifikanın bir parçası olan ekte tanımlanmış olup, ek bir sayfadan oluşmaktadır. Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No: M.5419.02
İlk Yayın Tarihi: 17 Nisan 2019
Son Yayın Tarihi: 14 Nisan 2021
Revizyon Numarası: 02
Son Geçerlilik Tarihi: 16 Nisan 2024

Bu sertifika kapsamında olan Sınıf Is ürünler için Kiwa Belgelendirme Hizmetleri A.Ş., Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.



Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

14 Nisan 2021, İstanbul, Türkiye

AT Sertifikası Eki:

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika No: 1984-MDD-19-588, Revizyon Numarası: 02

İlgili tıbbi cihazlar;

Ürün: Solunum Devreleri

Tipleri: Ventilasyon Devreleri, Anestezi Devreleri, Özel Devreler, Yarı Kapalı Devreler / APL Valfli Devreler, BPAP Devreler, IPPB Devreler, CPAP Devreler, Proksimal Basınç Hatlı Devreler, Coaxial Devreler, T Devreler, Chambers, Aspiyasyon Hortumları, BVM Resusitatörler, Gaz Örneklem Hatları, Devreler için Nebulizasyon Parçaları

Ürün: Isıtıcı Telli Devreler

Ürün: Anestezi Balonları

Ürün: Solunum Maskesi

Tipleri: Anestezi Maskeleri, Oksijen / Aerosol Terapi Maskeleri

Ürün: Filtre

Tipleri: Solunum Filtreleri

Ürün: IV Set ve Konnektörler

Tipleri: İnfüzyon Setleri, Uzatma Setleri, İnfüzyon Konnektörleri

Ürün: Kateter Mount

Ürün: Enjektör Kilit Adaptörü

Ürün: Biyosidal Aparatı

Kiwa Belgelendirme Hizmetleri A.Ş. Tıbbi Cihaz Yönetmeliği 93/42/AT altında bir onaylanmış kuruluş olup kimlik numarası 1984'tür.



Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

14 Nisan 2021, İstanbul, Türkiye

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-19-588

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

**MEDİTERA TIBBİ MALZEME
SANAYİ VE TİCARET ANONİM ŞİRKETİ**

İBNİ MELEK OSB. MH. TOSBİ YOL 4 SK. NO:29 35900 TİRE / İZMİR - TURKEY

Products: Breathing Circuits, Heated Wire Circuits, Anestheasia Bags, Breathing Masks, Filters, IV Sets ve Connectors, Catheter Mounts, Syringe Lock Adaptor, Biocidal Applicator

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5419.02

Date of first issue: 17 April 2019

Date of last issue: 14 April 2021

Revision Number: 02

Expiry Date: 16 April 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V for Class Is devices covered by this certificate.



14 April 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Enclosure of the EC Certificate:**Production Quality Assurance System according to****Medical Devices Directive 93/42/EEC Annex-V****Certificate Number: 1984-MDD-19-588, Revision Number: 02**

Concerned medical devices;

Product: Breathing Circuits**Types:** Ventilation Circuits, Anesthesia Circuits, Special Circuits, Semi-Closed Circuits / APL Valve Circuits, BPAP Circuits, IPPB Circuits, CPAP Circuits, Proximal Pressure Line Circuits, Coaxial Circuits, T Circuits, Chambers, Aspiration Tubes, BVM Resuscitators, Gas Sampling Lines, Nebulizer Parts for Breathing Circuits**Product:** Heated Wire Circuits**Product:** Anesthesia Bags**Product:** Breathing Masks**Types:** Anesthesia Masks, Oxygen / Aerosol Therapy Masks**Product:** Filters**Types:** Breathing Filters**Product:** IV Sets ve Connectors**Types:** Infusion Sets, Extension Lines, Infusion Connectors**Product:** Catheter Mounts**Product:** Syringe Lock Adaptor**Product:** Biocidal Applicator

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

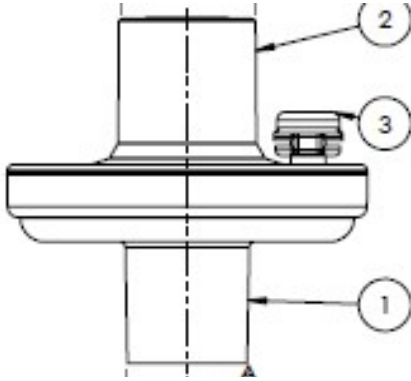


14 April 2021, Istanbul, Turkey

Head of Notified Body
Muhteşem Gökhan Yücel

1. Product Name and Product Code:

AL-080239.V001 Bacterial Viral Filter (STERILE EO)

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

Ethylene oxide sterilization. This product line is provided both as sterile

4. Packaging:

Tyvek packaging.

5. Intended Use and Functional Description :

6. AL-080239.V001 manufactured by Meditera, is a disposable, single-use barrier type, bi-directional filter fabricated from a plastic resin that is supplied to the customer packaged and non-sterile. Fabricated with a filtering medium that is highly effective in reducing the numbers of both bacterial and viral contaminants that may be present in a patient's exhaled gas, the device's design also minimizes the resistance to air flow. The product is intended to protect both the patient and machine from potential transmission of pathogens by droplets and aerosols.

7. Shelf life :

5 years from the date of production .

8. Product Description:

8.1. Classification: Class IIa Rule 2

8.2. This product does not contain any metallic parts

8.3. Spesification of the product :

Filter Code	Viral efficiency	Bacterial efficiency	Resistance to flow			Weight (gr)	Dead Space (ml)	Moisture output at 500 ml Vt	Tidal Volume (ml)
			30 lt/min	60 lt/min	90 lt/min				
AL-080239	>99.999%	>99.9999%	5mm H ₂ O	14 mm H ₂ O	27.6 mm H ₂ O	21	33	NA	150-1500

9. Standarts:

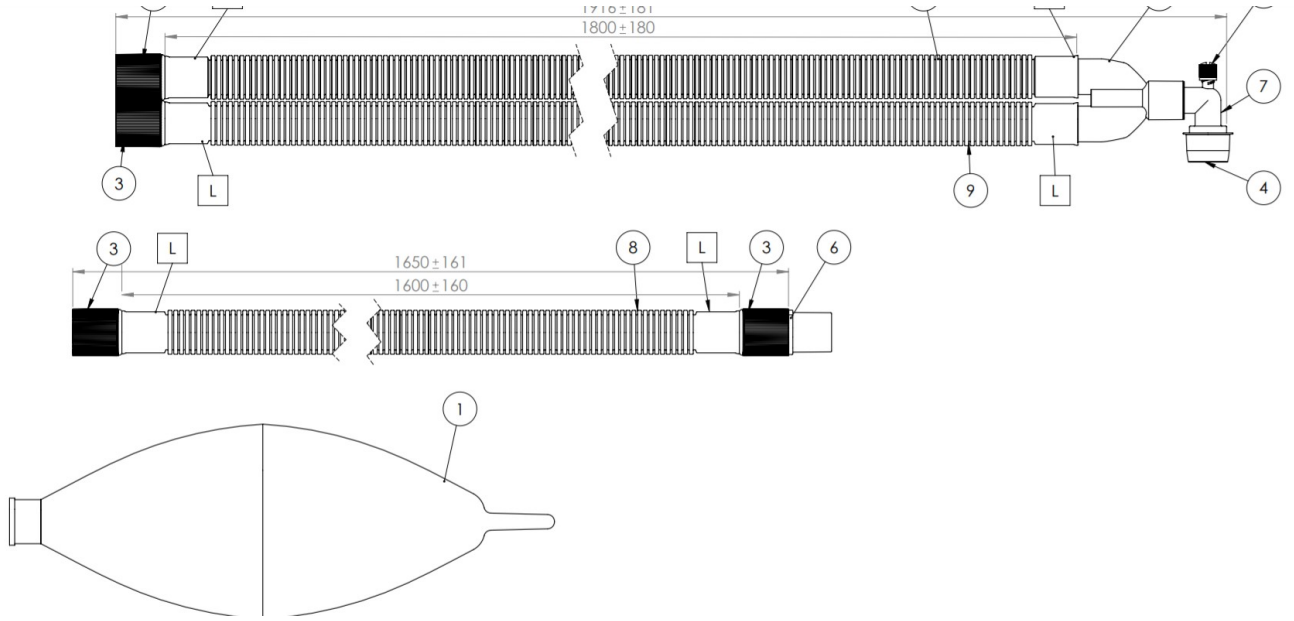
EN ISO 13485:2003, 93/42/EEC Medical Device Directive, EN ISO 9360-1:2009, EN ISO 9360-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2009, EN ISO11135-1:2007, EN ISO 23328-1, EN ISO 23328-2

10. Waste Method:

After use product will be “contaminated medical waste” and package will be “packaging waste” so they should be handled according to relevant national and international standards and regulations.

1. Product Name and Product Code:

AL-11019-060.V002- Adult Corrugated Circuit 180cm with limb and breathing bag (Sterile EO)

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

Ethylene oxide sterilization. This product line is provided both as sterile and nonsterile.

4. Packaging:

Tyvek packaging. ISO Class 8 Clean Room Manufactured

5. Intended Use and Functional Description :

Disposable circuits used to conduct medical gases from the anaesthesia system to the patient.

Anaesthetic gas exits the anaesthesia machine (via the common gas outlet) and then enters a breathing circuit. The function of the circuit is to deliver oxygen and anaesthetic gases to the patient and to eliminate CO₂. The CO₂ may be eliminated by gas inflow or by soda lime absorption.

6. Shelf life :

5 years from the date of production .

7. Product Description:

7.1. Classification: Class IIa Rule 2

7.2. This product does not contain any metallic parts

7.3. Specification of the product :

Item	Description	Quantity
150.07.040	2 LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER(RIGID PP CONNECTOR)	1,0
150.11.036	ELBOW CONNECTOR LUER CAP	1,0
151.03.001.01	22 MM STRAIGHT CONNECTOR	4,0
151.03.021.01	LONG CONNECTOR CAP RED	1,0
151.03.087.02	22 MM PARALLEL Y CONNECTOR W/OUT PORTS PP	1,0
151.03.110	22-22MM STRAIGHT CONNECTOR	1,0
151.03.178.01	ELBOW CONNECTOR WITH CO2 PORT PP	1,0
151.05.01.055	22 MM CORRUGATED TUBING PE 160 CM CUT	1,0
151.05.01.062	22 MM CORRUGATED TUBING PE 180 CM CUT	2,0

8. Standarts:

EN ISO 13485:2003, 93/42/EEC Medical Device Directive, EN ISO 5367, EN ISO 5356-1, EN ISO 11607-1:2009, EN ISO 11607-2:2009, EN ISO11135-1:2007, EN ISO 23328-1, EN ISO 23328-2,EN ISO 594-1

9. Waste Method:

After use product will be “contaminated medical waste” and package will be “packaging waste” so they should be handled according to relevant national and international standards and regulations.

	PRODUCT DESCRIPTION	PD08-03
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6.7. Double swivel patient connection

7. Applied Standarts:

EN ISO 13485, 93/43/EEC Medical Device Directive, ISO 12342, EN 5356, ISO 11135-1, ISO 10993-7, ISO 10993-1, EN ISO 11607-1, EN ISO 11607-2.

8. Tests performed on the product :

8.1. Dimensional controls (Gauge, caliper and weight controls)

8.2. Leakage

8.3. Resistance to flow

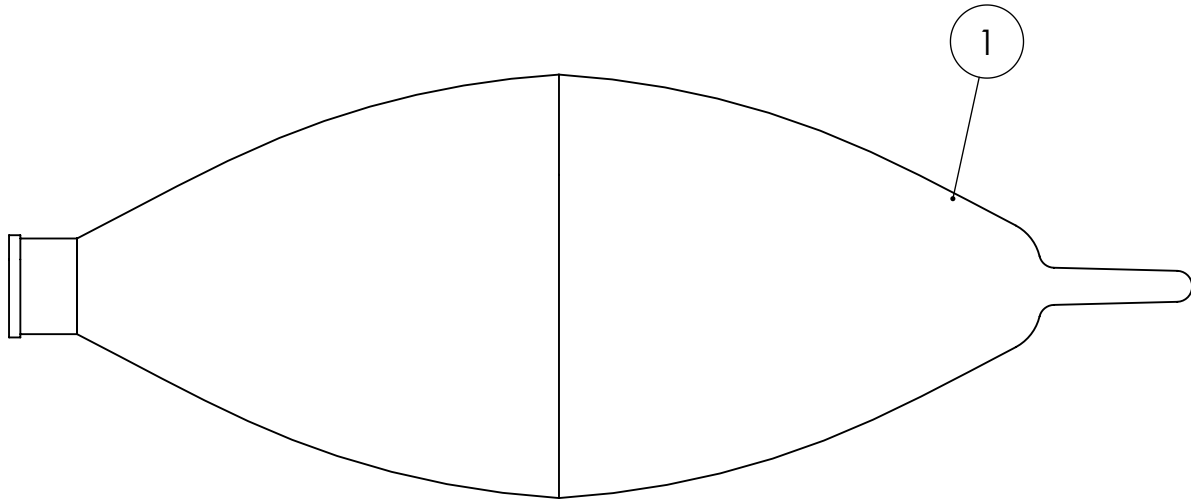
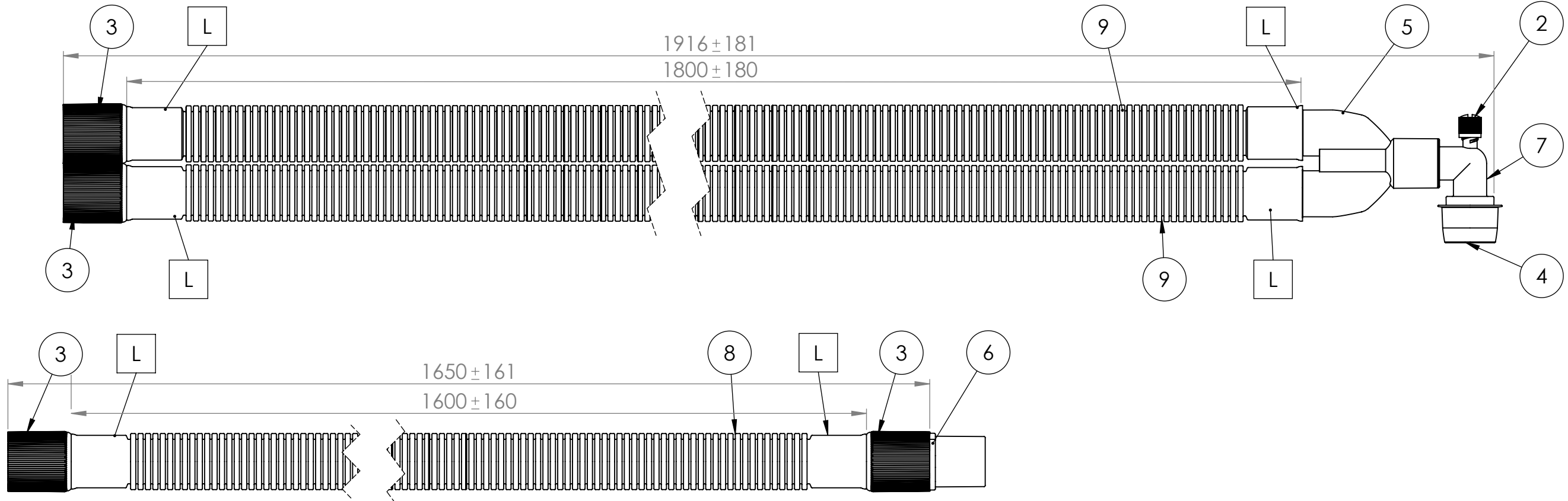
8.4. Routine assembling process controls

8.5. Pull test

8.6. Biocompatibility

8.7. Accelerated aging test

UNIT NO.	PART NUMBER	DESCRIPTION	QUANTIT Y
1	150.07.040	2 LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER(RIGID PP CONNECTOR)	1
2	150.11.036	ELBOW CONNECTOR LUER CAP	1
3	151.03.001.01	22 MM STRAIGHT CONNECTOR	4
4	151.03.021.01	LONG CONNECTOR CAP RED	1
5	151.03.087.02	22 MM PARALLEL Y CONNECTOR W/OUT PORTS PP	1
6	151.03.110	22-22MM STRAIGHT CONNECTOR	1
7	151.03.178.01	ELBOW CONNECTOR WITH CO2 PORT PP	1
8	151.05.01.055	22 MM CORRUGATED TUBING PE 160 CM CUT	1
9	151.05.01.062	22 MM CORRUGATED TUBING PE 180 CM CUT	2



stok adı stock name	BREATHING CIRCUIT (STERILE EO)	stok kodu stock code	AL-11019-060.V002
ölçek scale	1:2	revizyon no revision no	01
yerini aldığı replacement for	N/A	versiyon no occurs	001
sayfa page/of	1/1	tip type	Technical Drawing
prototip prototype	☒	onaylı approved	☒
revizyon notu revision text	Limb hatındaki balon limb hatından ayrı gösterildi.	üretimde in production	☒
açıklamalar descriptions	All dimensions are in millimeters	üretim dışı out of production	☒
hazırlayan author	23.1.2018	onaylayan approved	23.1.2018
isim name	Samet Öztürk	isim name	Ferda Sevinçli

SOLVENT SOLVENT	☒
%75 SOLVENT + %25 ALKOL %75 SOLVENT + %25 ALCOHOL	☒
ALKOL ALCOHOL	☒
LOCTITE LOCTITE	☒
SİLİKON SİLİKON	☒

ALTERA

8

7

6

5

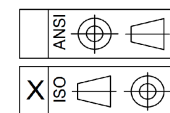
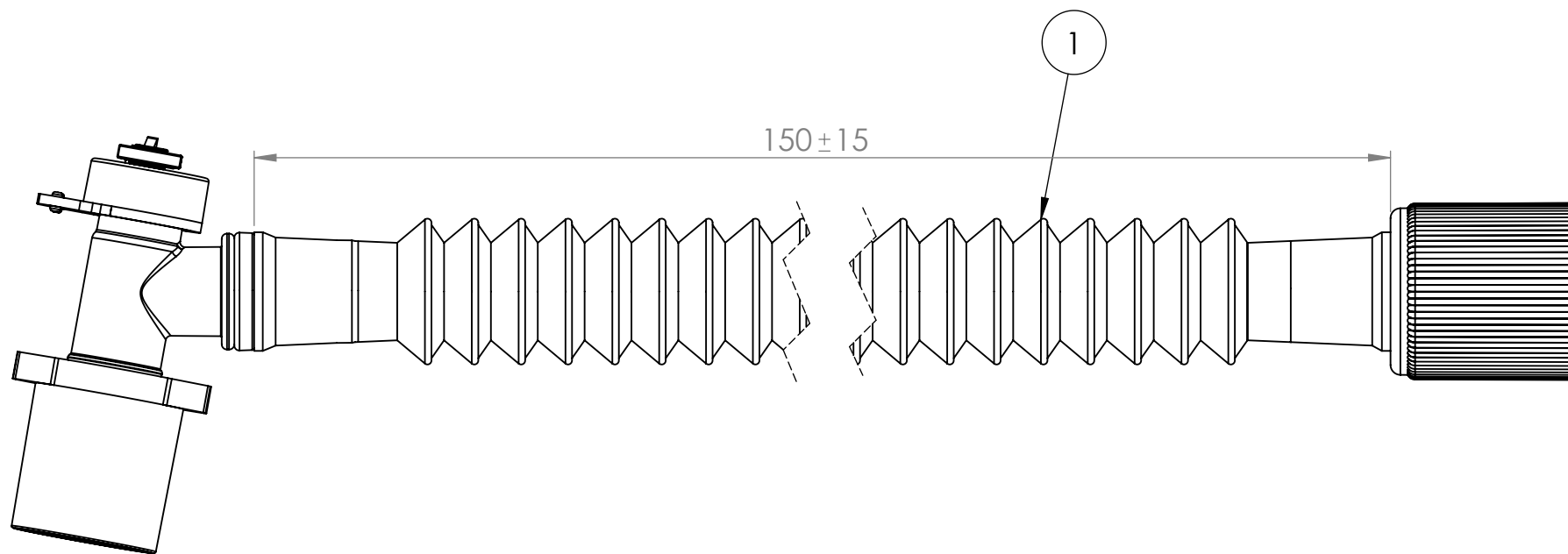
4

3

2

1

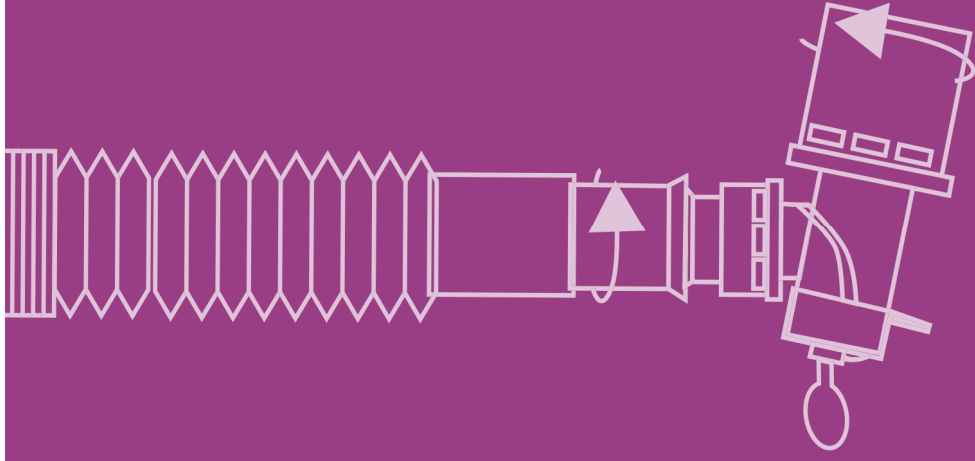
UNIT NO.	PART NUMBER	DESCRIPTION	QUANTITY
1	151.33.17300.01	CATHETER MOUNT	1



All dimensions are in millimeters

SOLVENT SOLVENT	S
%75 SOLVENT + %25 ALKOL %75 SOLVENT + %25 ALCOHOL	S+A
ALKOL ALCOHOL	A
LOCTITE LOCTITE	L
SİLİKON SILICON	Si

Antet güncellendi.					01	Samet Öztürk		Yusuf Pekgüzel			
Açıklamalar Notes					Revizyon no Revision no	Değiştirme yapan Changed By		Onaylayan Approved			
Genel Toleranslar Gen. Tolerances		Ölçek Scale	1:1	Ad Name	İmza Signature	Tarih Date					
N/A		Hazırlayan Prepared		Samet Öztürk		2.12.2019					
		Onaylayan Approved		Yusuf Pekgüzel		2.12.2019					
		Resim no Dwr.no		TD		Yayın no Release no				TDAL-17300.V001_1	
N/A		Parça Adı Part Name		CATHETER MOUNT (ALTECH)				Yayın tarihi Release date		09.04.2013	
		Parça Kodu Part Code		AL-17300.V001				Sheet / Sayfa 1		Total/Tamamı 1	
								S. Boyutu Drw.Size		A3	



Catheter Mounts

altech[®]

a Mediterra Company

Catheter Mounts

Altech range of catheter mounts includes a wide choice of smoothbore PVC and extendible configurations

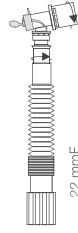
- Smoothbore products provide low resistance to flow while external coil reduces kinks and blockages. Besides they prevent fluid build up reducing risks of bacterial growth thanks ti smooth inner surface.

- Extendible PP product provides a lightweight and flexible solution and allows clinician to adjust the position of the catheter mount
- 360 degree double swivel connector increases ease of use
- Double cap helps to maintain PEEP during suctioning or bronchoscopy.
- Luer lock port for gas sampling
- 15M or 22F adapters available

Catheter Mounts

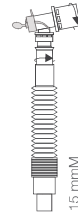


CATHETER MOUNT EXTENDIBLE



22 mmF

Dead space (ml): Close: 25, Open: 40

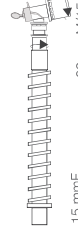


15 mmM

22 mmM/15mmF

Dead space (ml): Close: 25, Open: 40

CATHETER MOUNT SMOOTH BORE



22 mmM/15mmF

Dead space (ml): 30

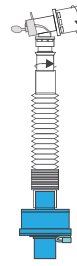


22 mmF

22 mmM/15mmF

Dead space (ml): 30

CATHETER MOUNT & FILTER

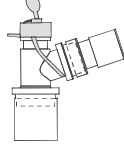


22 mmF

22 mmM/15mmF

Dead space (ml): Close: 103, Open: 117

CATHETER MOUNTS



15 mmM/22 mmF

22 mmF

15 mmM/22 mmF

22 mmF

SWIVEL CATHETER MOUNT

CODE: 67300	CODE: 66300	CODE: AL-10000
QTY/Box: 50	PVC-FREE CODE: P66300	QTY/Box: 100
Dead space (ml):	QTY/Box: 50	Dead space (ml): 3
Close: 22, Open: 37	Dead space (ml): 27	

CATHETER MOUNT SMOOTH BORE

Smoothbore

Length	Code	Qty/Box
15 cm/6"	AL-22300	50
15 cm/6"	AL-P22300	50
(PVC-free)		



22 mmF

22 mmM/15 mmF

22 mmF

Dead space (ml): 30



22 mmF

22 mmM/15 mmF

CATHETER MOUNT EXTENDIBLE

Extendible

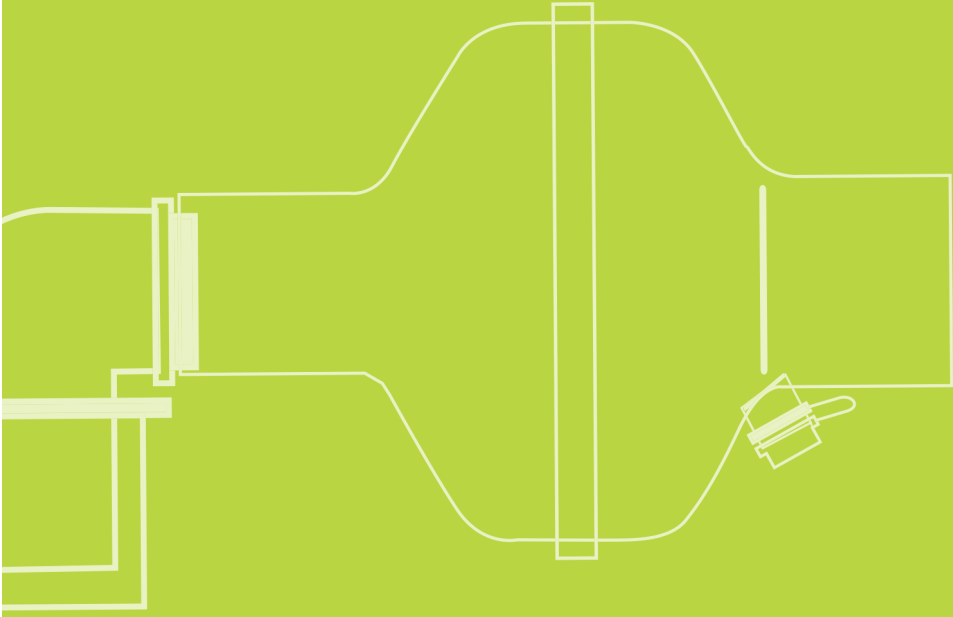
Length	Code	Qty/Box
15 cm/6"	AL-27300	50



22 mmF

22 mmM/15 mmF

Dead space (ml): Close: 25, Open: 40



altech[®]

a Mediterra Company

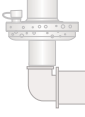
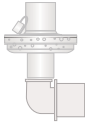
Filters

Bacterial Viral Filters

- Dedicated to the quality, committed to enhancing patient care Altech provides you with simple, cost effective, secure solutions and the best filtration efficiency for your respiratory patient.
- To help you minimize filtration challenges, we offer a comprehensive line of high-performance breathing filters.
- Each Altech branded filter provides its own unique advantages to maximize the clinical outcomes for filtration when used with multiple ventilator applications, such as noninvasive, invasive or anesthesia procedures.
- Our filters may help reduce the risk of possible hospital- or ventilator-acquired patient infections and may help create a safer environment for the caregiver by minimizing bacterial and viral particle penetration.



BACTERIAL-VIRAL FILTER		BACTERIAL-VIRAL FILTER	BACTERIAL-VIRAL FILTER
Code	SBC raw material	PP raw material	PP raw material
Sterile Code	AL-08002	AL-08018	AL-08023
Qty/Box	AL-080029	AL-080189	AL-080239
	50	50	50
Tidal volume (ml)	150-1500	150-1500	150-1500
Dead Space (ml)	77	33	33
Bacterial Efficiency	>99.999%	>99.999%	>99.999%
Viral Efficiency	>99.999%	>99.999%	>99.999%
Resistance to Flow	30 L/min 4.1 mm H ₂ O	30 L/min 4.3 mm H ₂ O	30 L/min 4.3 mm H ₂ O
	60 L/min 11.6 mm H ₂ O	60 L/min 12 mm H ₂ O	60 L/min 14 mm H ₂ O
	90 L/min 24.6 mm H ₂ O	90 L/min 25 mm H ₂ O	90 L/min 27.6 mm H ₂ O
Weight (gr)	23	19	21
Fittings	22mmM-15/22mmMF	22mmM - 15/22mmMF	22mmM - 15/22mmMF



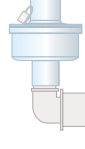
BACTERIAL-VIRAL FILTER		BACTERIAL-VIRAL FILTER	BACTERIAL-VIRAL FILTER
Code	SBC raw material	PP raw material	PP raw material
Sterile Code	AL-08002/1	AL-08018/1	AL-08023/1
Qty/Box	AL-080029/1	AL-080189/1	AL-080239/1
	45	45	45
Tidal volume (ml)	150-1500	150-1500	150-1500
Dead Space (ml)	80	36	36
Bacterial Efficiency	>99.999%	>99.999%	>99.999%
Viral Efficiency	>99.999%	>99.999%	>99.999%
Resistance to Flow	30 L/min 4.5 mm H ₂ O	30 L/min 4.5 mm H ₂ O	30 L/min 5.5 mm H ₂ O
	60 L/min 12 mm H ₂ O	60 L/min 12.5 mm H ₂ O	60 L/min 14.5 mm H ₂ O
	90 L/min 25 mm H ₂ O	90 L/min 25.5 mm H ₂ O	90 L/min 28 mm H ₂ O
Weight (gr)	28.5	24.5	26.5
Fittings	22mmM-15/22mmMF	22 mmM -15/22 mmMF	22 mmM -15/22 mmMF

Bacterial Viral HME Filters

- Bacterial Efficiency %99.9999
- High level of moisture output
- Small and paediatric versions
- Coupled with a hydrophobic bacterial viral filter membrane
- Rounded ergonomic housing
- Sterile or Clean
- Standard Retainable Monitoring Cap
- High level of moisture output(>33mgH₂O/L)
- Hydroscopic cellulose or foam HME Media
- ISO Standard Connectors
- Individually Packed



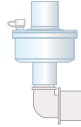
BACTERIAL-VIRAL/HME Filter		BACTERIAL-VIRAL/HME Filter with paper HME	BACTERIAL-VIRAL/HME Filter with foam HME
Code	SBC raw material	SBC raw material	SBC raw material
Sterile Code	AL-08006	AL-08016	AL-08020
Qty/Box	AL-080069	AL-080169	AL-080209
	50	50	50
Tidal volume (ml)	150-1500	150-1500	150-1500
Dead Space (ml)	77	53	53
Bacterial Efficiency	>99.999%	>99.999%	>99.999%
Viral Efficiency	>99.999%	>99.999%	>99.999%
Resistance to Flow	30 L/min 8.4 mm H ₂ O	30 L/min 9.4 mm H ₂ O	30 L/min 6 mm H ₂ O
	60 L/min 19.9 mm H ₂ O	60 L/min 23.2 mm H ₂ O	60 L/min 16.5 mm H ₂ O
	90 L/min 38.2 mm H ₂ O	90 L/min 42 mm H ₂ O	90 L/min 32 mm H ₂ O
Weight (gr)	24	30	24
Fittings	22 mmM-15/22 mmMF	22 mmM -15/22 mmMF	22 mmM -15/22 mmMF
Humidification efficiency	38.6mgH ₂ O/L (@500 ml tid, vol.)	36.8 mgH ₂ O/L (@500 ml tid, vol.)	37.5 mgH ₂ O/L (@500 ml tid, vol.)



BACTERIAL-VIRAL/HME Filter Angled		BACTERIAL-VIRAL/HME Filter Angled	BACTERIAL-VIRAL/HME Filter Angled
Code	SBC raw material	SBC raw material	PP raw material
Sterile Code	AL-08006/1	AL-08016/1	AL-08020/1
Qty/Box	AL-080069/1	AL-080169/1	AL-080209/1
	45	45	45
Tidal volume (ml)	150-1500	150-1500	150-1500
Dead Space (ml)	80	55	55
Bacterial Efficiency	>99.999%	>99.999%	>99.999%
Viral Efficiency	>99.999%	>99.999%	>99.999%
Resistance to Flow	30 L/min 4 mmvH ₂ O	30 L/min 8.5 mm H ₂ O	30 L/min 6.5 mmvH ₂ O
	60 L/min 17 mmvH ₂ O	60 L/min 23.5 mm H ₂ O	60 L/min 17 mmvH ₂ O
	90 L/min 32 mmvH ₂ O	90 L/min 42.5 mm H ₂ O	90 L/min 32.5 mmvH ₂ O
Weight (gr)	29.5	36	29.5
Fittings	22 mmM-15/22 mmMF	22 mmM-15/22 mmMF	22 mmM-15/22 mmMF
Humidification efficiency	33.6mgH ₂ O/L (@500 ml tid, vol.)	35 mgH ₂ O/L (@500 ml tid, vol.)	37.1 mgH ₂ O/L (@500 ml tid, vol.)

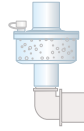
Bacterial Viral HME Filters

- Bacterial Efficiency %99.9999
- High level of moisture output
- Small and paediatric versions
- Coupled with a hydrophobic bacterial viral filter membrane
- Rounded ergonomic housing
- Sterile or Clean
- Standart Retainable Monitoring Cap
- High level of moisture output(>33mgH₂O/L)
- Hygroscopic cellulose or foam HME Media
- ISO Standart Connectors
- Individually Packed



BACTERIAL-VIRAL/HME
Filter with paper

Code	Sterile Code	PP raw material	BACTERIAL-VIRAL/HME Filter with foam HME
AL-08022	AL-080229	50	PP raw material
Qty/Box	50	150-1500	AL-080219
Tidal volume (ml)	55	>99.9999%	50
Dead Space (ml)	>99.9999%	>99.9999%	55
Bacterial-Viral Efficiency	>99.9999%	>99.9999%	50
Viral Efficiency	>99.9999%	>99.9999%	55
Resistance to Flow	30L/min 8.2 mm H ₂ O	30L/min 6.5 mm H ₂ O	50
	60L/min 21.4 mm H ₂ O	60L/min 17.2 mm H ₂ O	55
	90L/min 39.5 mm H ₂ O	90L/min 33 mm H ₂ O	50
Weight (gr)	35.6	28.5	50
Fittings	22mmM - 15/22mmMF	22mmM - 15/22mmMF	50
Humidification efficiency	37 mg H ₂ O/L (@500 ml tid, vol.)	35.5 mg H ₂ O/L (@500 ml tid, vol.)	50



BACTERIAL-VIRAL/HME
Filter Angled with paper

Code	Sterile Code	PP raw material	BACTERIAL-VIRAL/HME Filter Angled with foam HME
AL-08022	AL-080229	50	PP raw material
Qty/Box	50	150-1500	AL-080219
Tidal volume (ml)	55	>99.9999%	50
Dead Space (ml)	>99.9999%	>99.9999%	55
Bacterial-Viral Efficiency	>99.9999%	>99.9999%	50
Viral Efficiency	>99.9999%	>99.9999%	55
Resistance to Flow	30L/min 8.5 mm H ₂ O	30L/min 7 mm H ₂ O	50
	60L/min 21.5 mm H ₂ O	60L/min 17.5 mm H ₂ O	55
	90L/min 40 mm H ₂ O	90L/min 33.5 mm H ₂ O	50
Weight (gr)	41	34	50
Fittings	22mmM - 15/22mmMF	22mmM - 15/22mmMF	50
Humidification efficiency	37.5 mg H ₂ O/L (@500 ml tid, vol.)	36.5 mg H ₂ O/L (@500 ml tid, vol.)	50



Pediatric&Neonatal Filters

- Ideal electrostatic filtration performance
- Flat ergonomic design
- Small and light weight
- Cost effective
- Gas sampling port
- Optimised for pediatric and infant patients
- Effective solution on patient undergoing short term ventilation
- Latex free



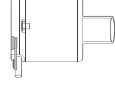
BACTERIAL VIRAL FILTER
PEDIATRIC

BACTERIAL VIRAL HME FILTER
PEDIATRIC

BACTERIAL VIRAL HME FILTER
NEONATAL

Code	Sterile Code	SBC raw material	BACTERIAL VIRAL HME FILTER PEDIATRIC	BACTERIAL VIRAL HME FILTER PEDIATRIC	BACTERIAL VIRAL HME FILTER NEONATAL
AL-08030	AL-080309	50	150-1200 ml	75-300ml	30-100 ml
Qty/Box	50	31 ml	29 ml	10 ml	10 ml
Dead Space (ml)	%99.9999	%99.9999	%99.9999	%99.9999	%99.9999
Bacterial-Viral Efficiency	%99.9999	%99.9999	%99.9999	%99.9999	%99.9999
Viral Efficiency	%99.9999	%99.9999	%99.9999	%99.9999	%99.9999
Resistance to Flow	30L/min - 8 mm H ₂ O	15L/min - 6 mm H ₂ O	5L/min - 6 mm H ₂ O	5L/min - 6 mm H ₂ O	5L/min - 6 mm H ₂ O
Weight (gr)	19	21	9	15 M-15F	15 M-15F
Fittings	22F-15M / 22M-15F	22F-15M / 22M-15F	22F-15M / 22M-15F	22F-15M / 22M-15F	22F-15M / 22M-15F
Humidification efficiency	-	@250ml TV 31 mg H ₂ O/L	@250ml TV 31 mg H ₂ O/L	@250ml TV 29 mg H ₂ O/L	@250ml TV 29 mg H ₂ O/L

Tracheostomy HME



Code	Sterile Code	Qty/Box	Moisture exchange surf.	Dead Space (ml)	Humidification efficiency	Resistance to Flow initial	Weight (gr)	Connections
AL-08025	AL-080259	100	500 cm ²	15	1hr: 27.5mgH ₂ O/L 24hr: 28.8mgH ₂ O/L	0.63 cmH ₂ O (30L/min) 1.8 cmH ₂ O (60 L/min) 3.5 cmH ₂ O (80 L/min)	8,4	15F, oxygen port: 5.5mm, suctioning port: 6.1mm
AL-08026	AL-080269	50	500 cm ²	15	1hr: 27.5mgH ₂ O/L 24hr: 28.8mgH ₂ O/L	0.63 cmH ₂ O (30L/min) 1.8 cmH ₂ O (60 L/min) 3.5 cmH ₂ O (80 L/min)	10	15F, oxygen port: 5.5mm, suctioning port: 6.1mm

- Central port for suctioning & sampling
- Extreme low resistance
- Suitable for adult and children
- Recommended use: for patients over 15kg.
- Paper Media