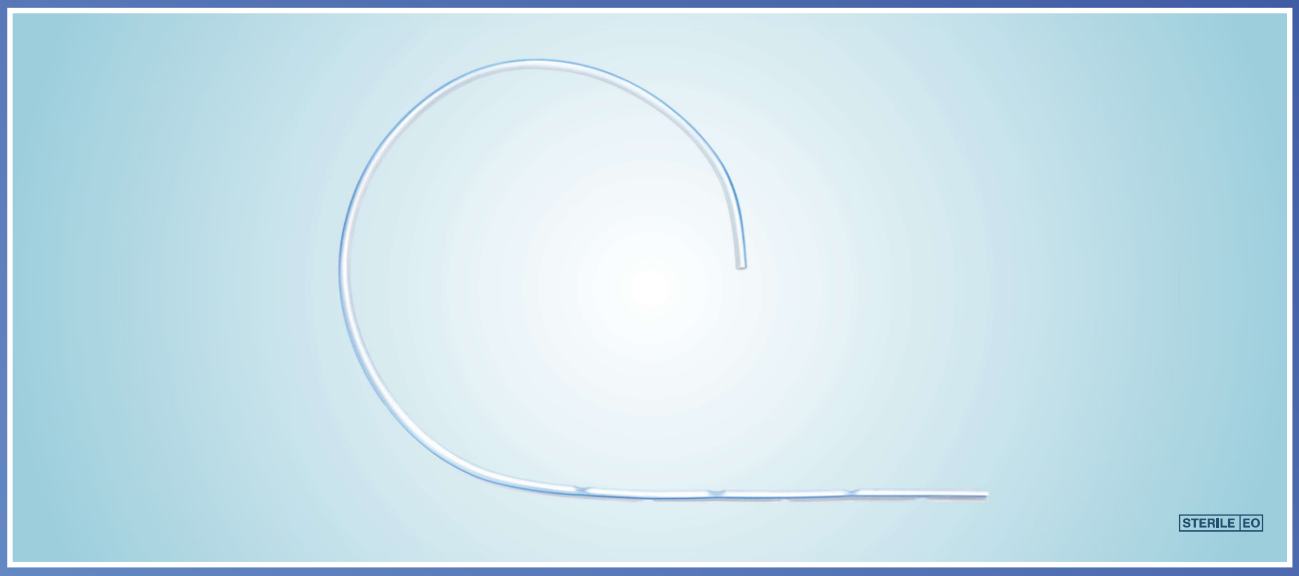
SILICONE DRAINS
Soft drains

Soft drains

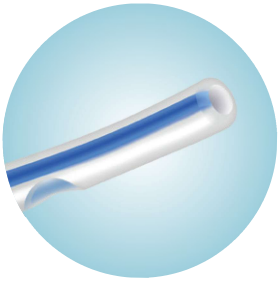
Soft drains are round drains made of medical grade silicone and used for open or half-open wound drainage via gravity.



Product features:

- Soft, medical grade silicone ensures good tissue compatibility
- Rounded, atraumatic tip
- 6 side openings
- With radiopaque stripe
- Length = 500 mm

Ch.	PU/SU	REF
8	25/100	**21899**
10	25/100	**21900**
12	25/100	**21901**
14	25/100	**21130**
15	25/100	**21902**
18	25/100	**21903**
20	25/100	**21131**
21	25/100	**21904**
24	25/100	**21905**
26	25/100	**21132**
27	25/100	**21906**
30	25/100	**21907**
33	25/100	**21908**
36	25/100	**21909**
39	25/100	**21133**



Soft drain

	Product Specification	REV: 05
		Page **1** of **3**

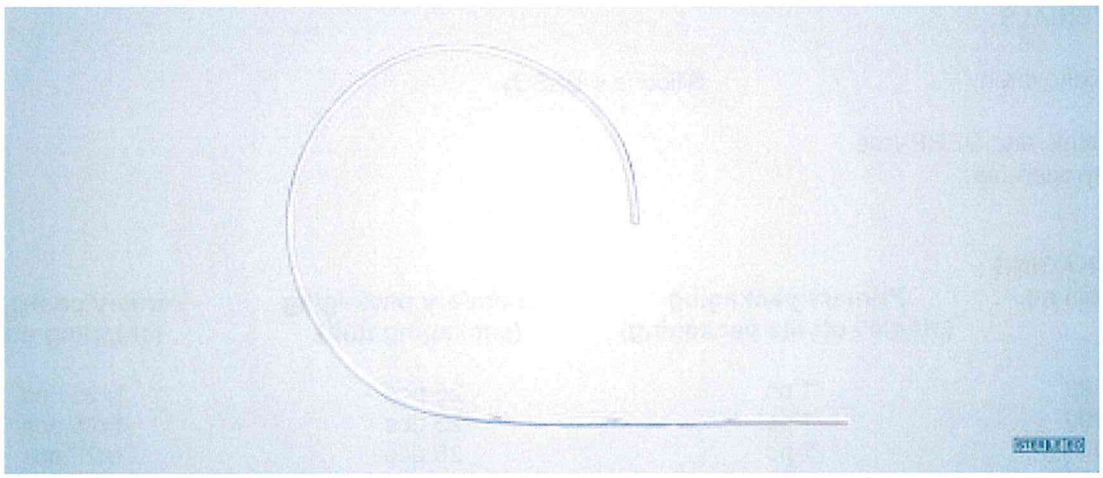
Silicone drains

21899	Silicone drain, L=500 mm, Ch.08
21900	Silicone drain, L=500 mm, Ch.10
21901	Silicone drain, L=500 mm, Ch.12
21130	Silicone drain, L=500 mm, Ch.14
21902	Silicone drain, L=500 mm, Ch.15
21903	Silicone drain, L=500 mm, Ch.18
21131	Silicone drain, L=500 mm, Ch.20
21904	Silicone drain, L=500 mm, Ch.21
21905	Silicone drain, L=500 mm, Ch.24
21132	Silicone drain, L=500 mm, Ch.26
21906	Silicone drain, L=500 mm, Ch.27
21907	Silicone drain, L=500 mm, Ch.30
21908	Silicone drain, L=500 mm, Ch.33
21909	Silicone drain, L=500 mm, Ch.36
21133	Silicone drain, L=500 mm, Ch.39

DESCRIPTION

Silicone drains consist of a plastic tube (L=500 mm) with a blue-colored radiopaque stripe, which is embedded in the material. They are provided with a rounded, atraumatic tip and 6 lateral openings at their proximal end. Silicone drains are available in different sizes (Ch. 08 / 10 / 12 / 14 / 15 / 18 / 20 / 21 / 24 / 26 / 27 / 30 / 33 / 36 / 39).

Silicone drains are supplied sterile.



Silicone drains

Prepared	Department: **VQ-RA**	Datum: **2021-01-18**	Signature: N. Löwen
Reviewed and released	Department: **VQ**	Datum: **2021-01-18**	Signature: J Adamietz

Silicone drains

CLASSIFICATION

In accordance with Rule 7 of Annex IX of the European Directive 93/42/EEC silicone drains are classified as medical devices Class IIa.

INTENDED USE

Silicone drains are intended for drainage of blood and exudates for treatment of post-surgery bleedings. They are suitable for wound drainage by means of gravity.

PROPERTIES

Material
The used material is highly soft and flexible and ensures good tissue compatibility. In addition, the transparent material allows easy visual inspection.

Perforation
The lateral openings avoid tissular ingrowth and, in this way, enable a continuous removal of blood and exudates.

Contrast stripe
The blue-colored, radiopaque contrast stripe allows position control by radiographic exams.

MATERIALS

Silicone drain: Silicone + $BaSO_4$

- Latex- and DEHP-free
- Pyrogen-free

PACKAGING

Item no.	Primary packaging (single / sterile packaging)	Secondary packaging (packaging unit)	Tertiary packaging (shipping unit)
21899	1 pc.	25 pcs.	1x25 pcs.
21900	1 pc.	25 pcs.	1x25 pcs.
21901	1 pc.	25 pcs.	1x25 pcs.
21130	1 pc.	25 pcs.	1x25 pcs.
21902	1 pc.	25 pcs.	1x25 pcs.
21903	1 pc.	25 pcs.	1x25 pcs.
21131	1 pc.	25 pcs.	1x25 pcs.
21904	1 pc.	25 pcs.	1x25 pcs.
21905	1 pc.	25 pcs.	1x25 pcs.
21132	1 pc.	25 pcs.	1x25 pcs.
21906	1 pc.	25 pcs.	1x25 pcs.
21907	1 pc.	25 pcs.	1x25 pcs.
21908	1 pc.	25 pcs.	1x25 pcs.
21909	1 pc.	25 pcs.	1x25 pcs.
21133	1 pc.	25 pcs.	1x25 pcs.

Silicone drains

Primary packaging:	sterile PE bag in peel packaging: consisting of medical grade paper and Polyester / PP foil
Secondary packaging:	cardboard folding carton
Tertiary packaging/Shipping unit:	corrugated cardboard folding carton

STERILIZATION

Sterilization is carried out with ethylene oxide in line with DIN EN ISO 11135:2020.
The method used for germ destruction satisfies the requirements of this standard.
The SAL (sterility assurance level) reaches a value of 10^{-6}.

STORAGE

Silicone drains must be stored in a cool and dry place and protected from dust according requirements concerning "Medical Devices".
When properly stored sterile peel packaging maintains sterility of the device until the specified expiry date.

SHELF LIFE

When properly stored Silicone drains have a shelf life of 5 years.

COMMENTS

Silicone drains are intended for single use.
Therefore, reprocessing / resterilization for reuse are not allowed, as reuse of the device may change its mechanical or biological features. This can cause device failure, allergic reactions or bacterial infections.

Do not use if the packaging is damaged as sterility of the device can not be guaranteed.

-END OF DOCUMENT-

Nuotraukos pavyzdinės

PentaSil MED-TECH ENGINEERING

SILICONE TUBING FOR MEDICAL USE
SILOPLUS MT - PEROXIDE CURED FORMULAS

Material	*Siloplus® Medical* (Peroxide Cured) Silicone (VMQ Quality – Medical Grade, Non-Recycled) for UltraSafe™ process
Appearance	Transparent
Colour	None
Shape	Circular
Temperature Range	-45°C to +180°C
Properties	Excellent heat stability, transparent, odourless, tasteless, non-toxic, sterilizable (plasma, steam, EtO a.o.), unmeltable, highly elastic, non deformable, top mechanical properties, top safety
Dimensions	From I.D. × O.D = 1,0 × 2,0 mm up to I.D. × O.D = 12,5 × 19,0 mm (over 150 combinations). Other dimensions after request
Uses	Suction (single use), liquid transportation & drainage in all human & veterinary surgical operations. Connection of all types medical equipment & devices
Length/ Package	25 m rolls (or other length on request) in PE transparent bags firmly sealed
Standards/ Certification	EN ISO 9001:2015, EN ISO 13485:2016, CE Mark
Classification	Class I (MDR 2017/745 EU)

Available Diameters Inner Ø × Outer Ø in mm	
1 × 2	7 × 13
2 × 4	8 × 11
3 × 5	8 × 12
3 × 6	8 × 13
4 × 7	8 × 14
4 × 8	9 × 12
5 × 8	9 × 13
5 × 9	10 × 14
6 × 9	10 × 15
6 × 10	10 × 18
6 × 12	11 × 16
7 × 10	12,5 × 19
7 × 11	and over 150 combi-nations
7 × 12	

Saugansatz Suction Handle Embout d'aspiration	**Absaugverbindungsschlauch** Suction connecting tube Flexible de raccord d'aspiration	**Art.-Nr.** Art. no. Art.-n°	**VPE/VSE** SPU/SSU UE/UC
Ohne Handgriff/ Without handle/ Sans poignée **10 mm**	**Ch.30, 3 m** Trichter - Trichter Funnel - Funnel Entonnoir - Entonnoir		
		35204	30/30
Mit Handgriff/ With handle/ Avec poignée **8 mm** P.d. 77	**Ch.30, 3 m** Trichter - Trichter Funnel - Funnel Entonnoir - Entonnoir		
		35203	30/30
Mit Handgriff/ With handle/ Avec poignée **8 mm**	**Ch. 30, 3,5 m** Trichter - Trichter Funnel - Funnel Entonnoir - Entonnoir		
		35303	30/30

Sistema operacinio lauko atsiurbimams
Yankauer tipo
Jungiamosios grandies ilgis 300 cm
Kaniulės diametras 8mm CH30

Alle Artikel sind auch als unsterile Bulkware lieferbar.

All articles can also be supplied as unsterile bulk material.

Tous les articles sont aussi livrables en modèle non stérile.

Hersteller

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Vertrieb

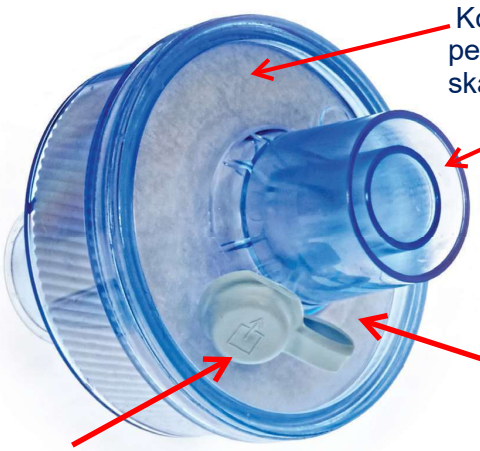
Revisionsstatus: 03/2020-10-20

97 Pirkimo dalis - Kombinuotas kvėpavimo filtras su drėgmės grąžinimu

Bacterial Viral HME Filters

- Bacterial Efficiency %99.9999 Efektyvumas 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 Kliniškai švarūs
- Standart Retainable Monitoring Cap
- High level of moisture output(>33mgH2O/L)
- Hygroscopic cellulose or foam HME Media
- ISO Standart Connectors
- Individually Packed

supakuoti po 1vnt.



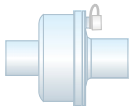
Korpusas permatomas, skaidrus

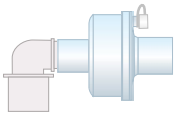
vientisos konstrukcijos

Luer Lock tipo jungtis CO2 matavimui, kurios anga turi fiksuotą dangtelį

BACTERIAL VIRAL HME FILTERS

Su šilumos ir drėgmės reguliatoriumi

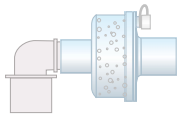


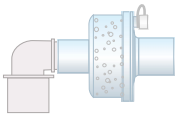


p.d. Kombinuotas kvėpavimo filtras su drėgmės grąžinimu

	BACTERIAL-VIRAL/HME Filter with paper	BACTERIAL-VIRAL/HME Filter with foam HME
	PP raw material	PP raw material
Code	AL-08022	AL-08021
Sterile Code	AL-080229	AL-080219
Qnty/Box	50	50
Tidal volume (ml) minimalus kvėpimo tūris	150-1500	150-1500
Dead Space (ml) filtro tūris	55	55
Bacterial-Viral Efficiency	>99,9999%	>99,9999%
Viral Efficiency	>99,999%	>99,999%
Resistance to Flow	30lt/min 8,2 mm H_2O	30lt/min 6,5 mm H_2O
pasipriešinimas	60lt/min 21,4 mm H_2O	60lt/min 17,2 mm H_2O
	90lt/min 39,5 mm H_2O	90lt/min 33 mm H_2O
Weight (gr)	35,6	28,5
Fittings	22mmM - 15/22mmMF	22mmM - 15/22mmMF
Humidification efficiency	37 mg H_2O/L (@500 ml tid. vol.)	35,5 mg H_2O/L (@500 ml tid. vol.)

136.1.9. drėgmės gražinimas





	BACTERIAL-VIRAL/HME Filter Angled with paper	BACTERIAL-VIRAL/HME Filter Angled with foam
	PP raw material	PP raw material
Code	AL-08022/1	AL-08021/21
Sterile Code	AL-080229/1	AL-080219/1
Qnty/Box	45	45
Tidal volume (ml)	150-1500	150-1500
Dead Space (ml)	57	57
Bacterial-Viral Efficiency	>99,9999%	>99,9999%
Viral Efficiency	>99,999%	>99,999%
Resistance to Flow	30lt/min 8,5 mm H_2O	30lt/min 7 mm H_2O
	60lt/min 21,5 mm H_2O	60lt/min 17,5 mm H_2O
	90lt/min 40 mm H_2O	90lt/min 33,5 mm H_2O
Weight (gr)	41	34
Fittings	22mmM - 15/22mmMF	22mmM - 15/22mmMF
Humidification efficiency	37,5 mg H_2O/L (@500 ml tid. vol.)	36,5 mg H_2O/L (@500 ml tid. vol.)

ENGLISH

USER MANUAL FOR FILTER
The following instructions are provided for maximum performance and safety in use of breathing filters.
Description: vienkartinis
Single patient use HME and antibacterial/viral filter for breathing circuits in anesthesia, reanimation and intensive care for bacterial and viral filtration as well as humidification of patient airways.
Instruction for use:
Connect the device securely to breathing system, catheter mount, anesthesia/ventilator machine, closed suction system ensuring that the connections are tight and safe. Also check if present perfect seal of the cap for capnometry port.
Warnings:
Please perform control tests for any blockage and leakage on the product and all respiratory line before starting the treatment.
1. The filter has been manufactured for single patient use and maximum recommended hours of use is 24 hours.
2. This filter is only used between the patient and breathing circuit.
3. The product is manufactured under clean room conditions. Do not use if the product and product package is damaged.
4. This product should be used only and exclusively under supervision of a physician.
5. Replace the filter in the event of increased resistance due to secretion from the patient.
6. The additional dead space of this device must be taken into consideration when used.
The product is latex-free.

DEUTSCH

FILTER GEBRAUCHSANWEISUNG
Die nachfolgende Gebrauchsanweisung ist dafür vorgesehen eine maximale Leistung und Sicherheit beim Einsatz von Atemfiltern zu gewährleisten.
Beschreibung:
Einsatz in Anästhesie, Reanimation und Intensivmedizin für bakterielle und virale Filterung sowie Befeuchtung des Atemkreislaufes als Einweg HME und / oder Bakterielles /Virales Filter.
Gebrauchsanweisung:
Verbinden Sie das Filter, indem Sie sicherstellen, dass die Verbindungstellen sicher und stabil sind, das geschlossene Absaugsystem, Anästhesie – Belüftungseinrichtung an die Katheter-Verbindung oder an die Beatmungsmaschine. Falls vorhanden, stellen Sie sicher, dass der Stecker des Kapnometer Ports fest verschlossen ist.
Hinweise:
Führen Sie Kontrolltests durch, um festzustellen, ob das Produkt oder die Atemleitung verstopft oder undicht ist, bevor Sie die Anwendung starten.
1. Das Filter wurde für einen Einweggebrauch hergestellt und die empfohlene Maximale Benutzungsdauer beträgt 24 Stunden.
2. Das Filter darf nur zwischen dem Patienten und dem Atemkreislauf benutzt werden.
3. Das Produkt wurde gemäß Reinraumbedingungen hergestellt. Falls das Produkt und die Verpackung des Produktes beschädigt ist, das Produkt bitte nicht benutzen.
4. Das Produkt darf nur und ausschließlich unter Aufsicht eines Facharztes benutzt werden.
5. Filter, dessen Resistenz aufgrund der Sekrete des Patienten erhöht wurde, sollten mit Neuen ersetzt werden.
6. Beim Gebrauch dieses Gerätes, muss der zusätzliche Tod-Raum des Produktes berücksichtigt werden.
Dieses Produkt enthält kein Latex

FRANÇAIS

GUIDE D'UTILISATION DU FILTRE
Les instructions suivantes sont fournies pour une performance maximale et la sécurité dans l'utilisation des filtres respiratoires.
Description :
L'humidificateur de filtre antibactérien viral HME pour les circuits d'anesthésie, réanimation et de thérapie intensive pour le filtrage de type électrostatique virale et bactérien ainsi que pour l'humidification de l'air.
Mode d'emploi :
Branchez l'appareil sûrement au système de respiration, au support pour cathéter mount, au dispositif d'anesthésie/ventilateur et au système fermé d'aspiration en s'assurant que les raccordements sont bien serrées et sécurisées. Vérifiez également si l'étanchéité du bouchon est parfaite pour l'accès a la capnométrie.
Avertissement:
Avant de commencer l'utilisation réaliser les tests de contrôle pour voir s'il existe ou non d'obstruction ou de fuite quelconque dans le produit ou la voie de d'aspiration.
1. Le filtre est fabriqué pour un usage unique sur un seul patient et la durée d'utilisation maximale recommandée est de 24 heures.
2. Le filtre est utilisé seulement entre le patient et le circuit de la respiration.
3. Le produit est fabriqué et conditionné dans les circonstances de salle blanche. Si le produit et l'emballage du produit sont endommagés, ne pas utiliser le produit.
4. Le produit doit absolument être utilisé sous la surveillance d'un médecin.
5. Remplacez, s'il vous plaît, les filtres dans le cas d'une résistance accrue due à des sécrétions chez le patient.
6. L'espace mort supplémentaire résultant de cet appareil doit être tenu compte.
Le produit non contient pas de latex.

ITALIANO

MANUALE D'USO DEI FILTRI
Le seguenti istruzioni hanno lo scopo di fornire le massime prestazioni e la sicurezza nell'utilizzo dei filtri respiratori.
Descrizione:
Il filtro monouso HME e/o batterico/virale viene utilizzato nel circuito respiratorio per la filtrazione batterica / virale e l'umidificazione in anestesia, rianimazione e terapia intensiva.
Istruzioni per l'uso:
Collegare il dispositivo al sistema respiratorio, all'attacco del catetere, al dispositivo di ventilazione – anestesia oppure al sistema di aspirazione chiuso assicurandosi che i collegamenti siano saldi e sicuri. Inoltre, se presente, assicurarsi che la presa del capnometro sia ben chiusa.

AVVERTENZE:
Prima di iniziare l'applicazione, si prega di eseguire i test di controllo per determinare se vi sono ostruzioni oppure perdite nel prodotto o nelle vie respiratorie.
1.Il filtro è stato fabbricato per utilizzo in un singolo paziente e la durata massima raccomandata d'utilizzo è 24 ore.
2.Il filtro viene utilizzato solo fra paziente e circuito respiratorio.
3.Il prodotto è fabbricato in condizioni di camera bianca. Non utilizzare il prodotto se la confezione risulta danneggiata.
4.Il prodotto si deve usare sempre ed assolutamente sotto la supervisione di un medico.
5.Sostituire il filtro in caso di aumento di resistenza dovuta alla secrezione dal paziente.
6.Nell'uso di questo dispositivo, lo spazio morto addizionale risultante dal dispositivo deve essere preso in considerazione.
Questo prodotto è privo di lattice.

97 p.d.

To whom it may concern ;

AL-08021.V001 coded product is a bacterial viral HME Filter formed of polypropylene housing ,

electrostatic filtration membrane and polyurethane foam HME element .

Elektrostatinis filtro veikimo principas

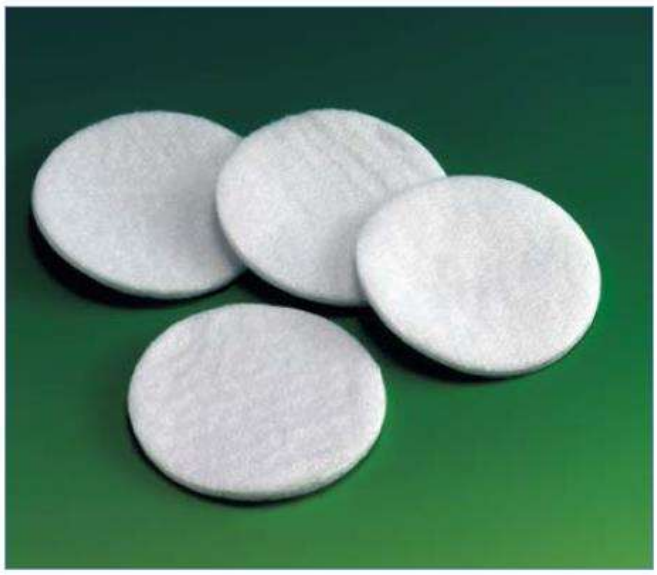
Product description:

AL-08021.V001 Bacterial Viral HME Filter is designed to reduce possible air or liquid borne cross contamination with microorganisms via airway devices like anesthesia machines,ventilators,home care ventilators for the patients under invasive or non-invasive ventilation.. The strategic use of an effective breathing filter protects, bi-directionally, both the patient and equipment.

AL-08021.V001 Bacterial Viral HME Filter contains an electrostatic filter pad and consists of a plastic body which incorporates 22 female / 15 male connectors in accordance with EN ISO 5326 and a luerlock connector which may only be used for gas monitoring. The filter is designed to combine the feature of reducing possible cross contamination with micro-organisms and an ideal heat and moisture return.

AL-08021.V001 consists of non-woven polypeopylene membrane inside the filter as shown below

With the efficiency of %99.9999 bacterial and %99.999 viral efficiency .



97 p.d.

07.12.2021

To whom it may concern,

We hereby declare that AL-08021 breathing filters HME:

-Have conical connetors: : 22F/15M, 22M/15F

Jungtys 22F/15M-22M/15F

Best Regards

Meditera®
TIBBİ MALZEME SANAYİ ve TİCARET A.Ş.
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