

1. Product Name and Product Code:

AL-080229.V001 BACTERIA HME FILTER WITH SOFT CAP PP (STERILE EO)

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

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

4. Packaging:

Tyvek packaging.

5. Intended Use and Functional Description :

Disposable devices used to conduct medical gases from the anaesthesia system to the patient. Breathing filters are barriers that separate patient environment from outside. This product filters the air inhaled and exhaled by the patient. By this way it provides microbiological protection for both patient and appliers in the hospitals.

The electrostatic filter has PP raw material and luer port for CO2 sample.

It has been manufactured for single patient use and maximum recommended hours of use is 24 hours.

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 :

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-080229	>99.999%	>99.9999%	8.2mm H ₂ O	21.4mm H ₂ O	39.5mm H ₂ O	35.6	55	37 mg/L	150-1500



BACTERIAL-VIRAL/HME

Filter with paper

PP raw material

Code	AL-08022
Sterile Code	AL-080229
Qty/Box	50
Tidal volume (ml)	150-1500
Dead Space (ml)	55
Bacterial-Viral Efficiency	>99,9999%
Viral Efficiency	>99,999%
Resistance to Flow	30lt/min 8,2 mm H ₂ O 60lt/min 21,4 mm H ₂ O 90lt/min 39,5 mm H ₂ O
Weight (gr)	35,6
Fittings	22mmM - 15/22mmMF
Humidification efficiency	37 mg H ₂ O/L (@500 ml tid. vol.)

8. Standarts:

EN ISO 13485:2016, 93/42/EEC Medical Device Directive, EN 556-1:2001, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 23328-1, EN ISO 23328-2

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.

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