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 seperates 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 .

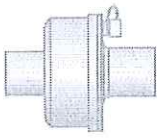
7. Product Description:

7.1. Classification: Class IIa Rule 2

7.2. This product does not contain any metalic parts

7.3. 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-080229	>99.999%	>99.9999%	8.2mm H_2O	21.4mm H_2O	39.5mm H_2O	35.6	55	37 mg/L	150-1500



	BACTERIAL-VIRAL/HME Filter with paper
	PP raw material
Code	AL-08022
Sterile Code	AL-080229
Qnty/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_2O
	60lt/min 21,4 mm H_2O
	90lt/min 39,5 mm H_2O
Weight (gr)	35,6
Fittings	22mmM - 15/22mmMF
Humidification efficiency	37 mg H_2O/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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