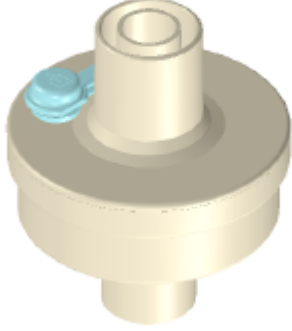


1. Product Name and Product Code:

AL-08022.V001 Bacterial Viral HME Filter (Non- Sterile)

**2. Manufacturer:**

Altera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

This product line is provided both as sterile and nonsterile. 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 separates 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.

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-08022	>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

8. 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

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.