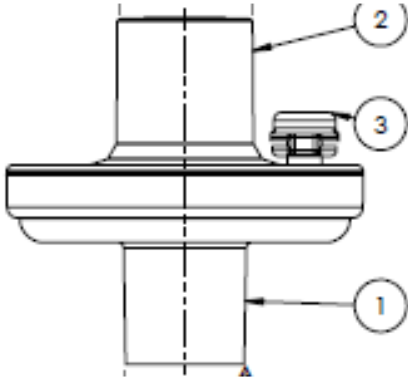


1. Product Name and Product Code:

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

**2. Manufacturer:**

Altera 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 Altera, 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. 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-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.