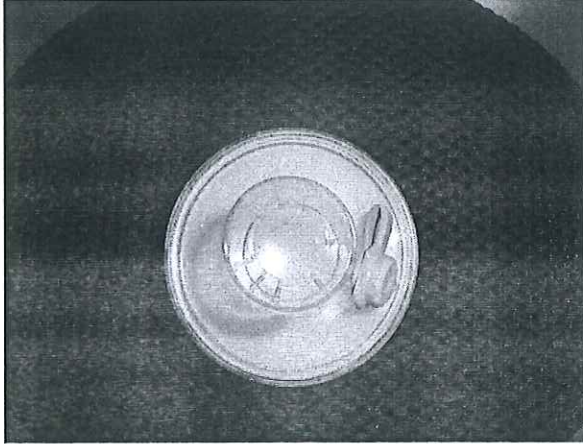


**1. Product Name and Product Code:**

AL-080189.V001 Bacterial Viral Filter with Soft Cap (Sterile EO)

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

**3. Sterilization Method :**

Ethylene oxide sterilization.

**4. Packaging:**

Tyvek packaging.

**5. Intended Use and Functional Description :**

6. AL-080189.V001 manufactured by Meditera, 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.

The filter is transparent and has SBC raw material.

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

### 7. Shelf life :

5 years from the date of production .

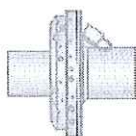
### 8. Product Description:

8.1. Classification: Class IIa Rule 2

8.2. This product does not contain any metallic parts

8.3. 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-080189   | >99.999%         | >99.9999%            | 4,3mm H <sub>2</sub> O | 12 mm H <sub>2</sub> O | 25 mm H <sub>2</sub> O | 19          | 33              | NA                           | 150-1500          |



#### BACTERIAL-VIRAL FILTER

|                      |                                  |
|----------------------|----------------------------------|
|                      | SBC raw material                 |
| Code                 | AL-08018                         |
| Sterile Code         | AL-080189                        |
| Qty/Box              | 50                               |
| Tidal volume (ml)    | 150-1500                         |
| Dead Space (ml)      | 33                               |
| Bacterial Efficiency | >99,9999%                        |
| Viral Efficiency     | >99,999%                         |
| Resistance to Flow   | 30 L/min 4,3 mm H <sub>2</sub> O |
|                      | 60 L/min 12 mm H <sub>2</sub> O  |
|                      | 90 L/min 25 mm H <sub>2</sub> O  |
| Weight (gr)          | 19                               |
| Fittings             | 22mmM - 15/22mmMF                |

**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.

**MEDİTERA İZMİR MALZEME  
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