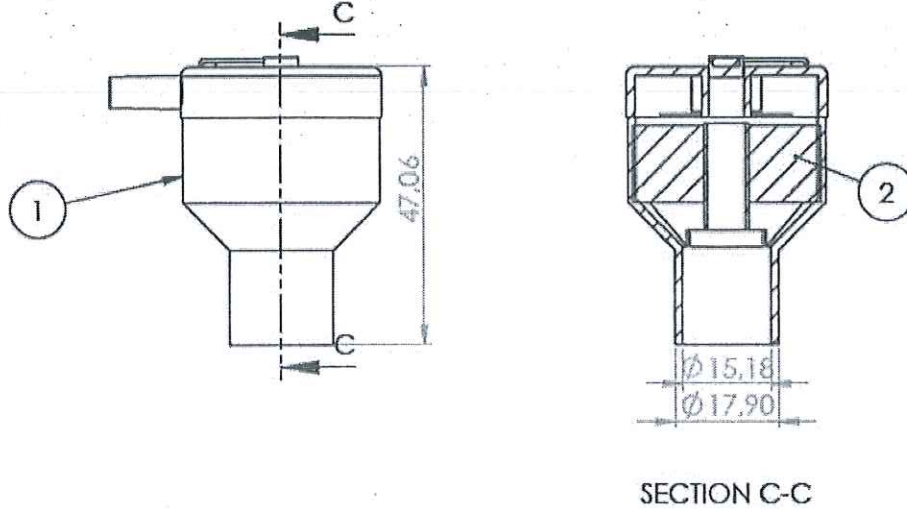


1. Product Name and Product Code:

AL-080259.V001 -Tracheostomy HME (Sterile)

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Packaging:

Product is packed individually. This tyvek package has two layer, one side is Film which is general thermoforming packaging material for medical devices. The other side is medical paper which is designed to be used as a porous lidding material in medical packages and as a porous web in industrial, medical pouches.

4. Intended Use and Functional Description:

Designed for only spontaneously breathing tracheostomized patients. The cellulose paper inside hold the warmed and moistened exhaled air and revert back to patient during inspiratory phase

5. Production Environment:

This product is produced according to the requirements of the ISO13485 and the MDD 93/42/EEC in a validated and monitored cleanroom class 8 according to the EN ISO 14644-1 "cleanrooms and associated controlled environments - Part1: Classification of air cleanliness"

6. Sterilization:

This products are supplied sterile to the customer. ETO, according to ISO 11135-1.

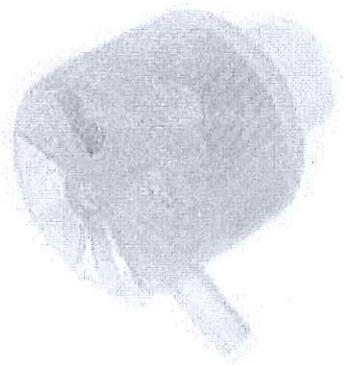
7. Time of usage:

The shelf-life of this product is 5 year, if the products are stored under normal conditions (dry and room temperature in original packaging) the expiration date is printed on the packaging label.

8. Product Description:

- 8.1. Classification: Class IIa Rule 2
- 8.2. GMDN Number: 37597, 35530
- 8.3. Raw Materials List: PP, Moist keeping medical grade paper.
- 8.4. This product does not contain any metallic parts
- 8.5. Volume of the product: Dead space is 15 ml.
- 8.6. 1.8 cmH₂O resistance to flow @60L/min flow
- 8.7. Weight:8.4 grams
- 8.8. For use on adult and pediatric patient above 15kg
- 8.9. Device can be used for a maximum period of 24 hours.
- 8.10. central port with clip cap for healing the tracheostomy tube without removing it from the patient

Tracheostomy HME



- Central port for suctioning & sampling
- Extreme low resistance
- Suitable for adult and children
- Recommended use; for patients over 15kg.
- Paper Media



Tracheostomy

HME	
Code	AL-08025
Sterile Code	AL-080259
Qty/Box	100
Moisture exchange surf.	500 cm ²
Dead Space (ml)	15
Humidification efficiency	1hr: 27,5mgH ₂ O/L 24hr: 28,8mgH ₂ O/L
Resistance to Flow initial	0.63 cmH ₂ O (30L/min) 1.8 cmH ₂ O (60 L/min) 3.5 cmH ₂ O (90 L/min)
Weight (gr)	8,4
Connections	15F, oxygen port: 5,5mm, suctioning port: 6,1mm

9. Applied Standards:

10. 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

11. Tests performed on the product :

- 11.1. Dimensional controls(Gauge, caliper and weight controls)
- 11.2. Routine assembling process controls
- 11.3. Accelerated aging test

12. Warnings:

Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

**MEDİTERA TIBBİ MALZEME
SAN. VE TİC. A.Ş.**

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