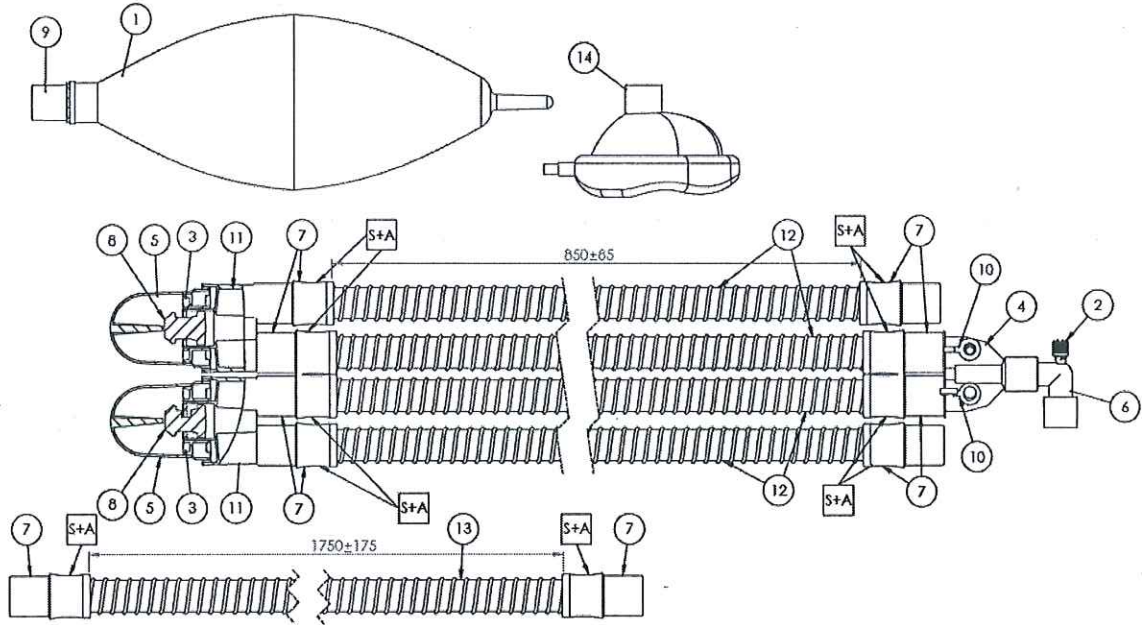


1. Product Name and Product Code:

AL-1222-070.V001

Adult Breathing Circuit Smoothbore PVC Tube with double water traps, limb breathing bag and mask

**2. Manufacturer:**

Meditera Tibbi Malzeme Sanayi ve Ticaret A.Ş.

3. Sterilization Method :

Ethylene oxide sterilization. This product line is provided both as sterile and nonsterile.

4. Packaging:

Nylon packaging. ISO Class 8 Clean Room Manufactured

5. Intended Use and Functional Description :

Disposable circuits used to conduct medical gases from the anaesthesia system to the patient. Anaesthetic gas exits the anaesthesia machine (via the common gas outlet) and then enters a breathing circuit. The function of the circuit is to deliver oxygen and anaesthetic gases to the patient and to eliminate CO₂. The CO₂ may be eliminated by gas inflow or by soda lime absorption.

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 :

UNIT NO.	PART NUMBER	DESCRIPTION	QUANTITY
1	150.07.040	2LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER(RIGID PP CONNECTOR)	1
2	150.11.036	ELBOW CONNECTOR LUER CAP	1
3	151.03.076	WATER TRAP SEAL	2
4	151.03.150	22 MM PARALLEL Y CONNECTOR PP	1
5	151.03.212	22MM WATER TRAP GLASS PART 4 CAVITY	2
6	151.03.224.01	ELBOW CONNECTOR WITH PORT PP	1
7	151.03.248	22M/22F STRAIGHT CONNECTOR PVC NEW	10
8	151.03.249	WATER TRAP CAP NEW	2
9	151.03.255	22-22 MM STRAIGHT CONNECTOR (NEW)	1
10	151.03.264	Y CONNECTOR CAP (NEW)	2
11	151.03.270	WATER TRAP PART	2
12	151.05.01.002	19 MM SMOOTHBORE TUBING 85 CM CUT PVC	4
13	151.05.01.005	19 MM SMOOTHBORE TUBING 175 CM CUT PVC	1
14	AL-09005	ANESTHESIA MASK #5	1

8. Standards:

EN ISO 13485:2003, 93/42/EEC Medical Device Directive, EN ISO 5367, EN ISO 5356-1, EN ISO 11607-1:2009, EN ISO 11607-2:2009, EN ISO 11135-1:2007, EN ISO 23328-1, EN ISO 23328-2, EN ISO 594-1

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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