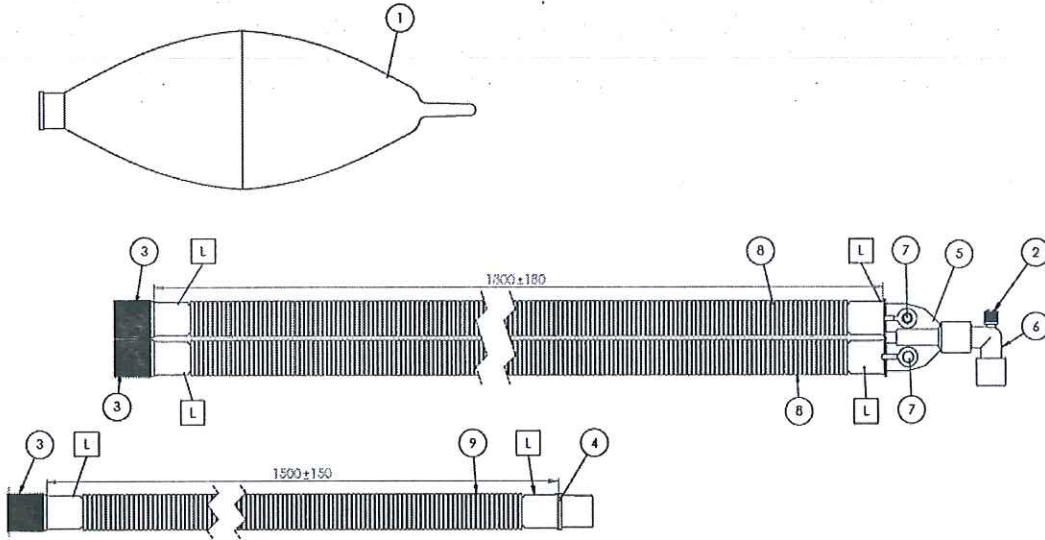


1. Product Name and Product Code:

AL-11019-060.V002- Adult Corrugated Circuit 180cm with limb and breathing bag (Sterile EO)

**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:

Tyvek 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 | 2 LT NEOPRENE SINGLE FOLDED BREATHING BAG WITH STICKER(RIGID PP CONNECTOR) | 1 |
| 2 | 150.11.036 | ELBOW CONNECTOR LUER CAP | 1 |
| 3 | 151.03.261 | 22 MM STRAIGHT CONNECTOR EVA (NEW) | 3 |
| 4 | 151.03.255 | 22-22 MM STRAIGHT CONNECTOR (NEW) | 1 |
| 5 | 151.03.150 | 22 MM PARALLEL Y CONNECTOR PP | 1 |
| 6 | 151.03.224.01 | ELBOW CONNECTOR WITH PORT PP | 1 |
| 7 | 151.03.264 | Y CONNECTOR CAP (NEW) | 2 |
| 8 | 151.05.01.062 | 22 MM CORRUGATED TUBING PE 180 CM CUT | 2 |
| 9 | 151.05.01.074 | 22 MM CORRUGATED TUBING PE 150 CM CUT | 1 |

8. Standarts:

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 ISO11135-1:2007, 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.