1. PRODUCT NAME & CODE

AL-1300.V011 Adult Extendible Breathing Circuit

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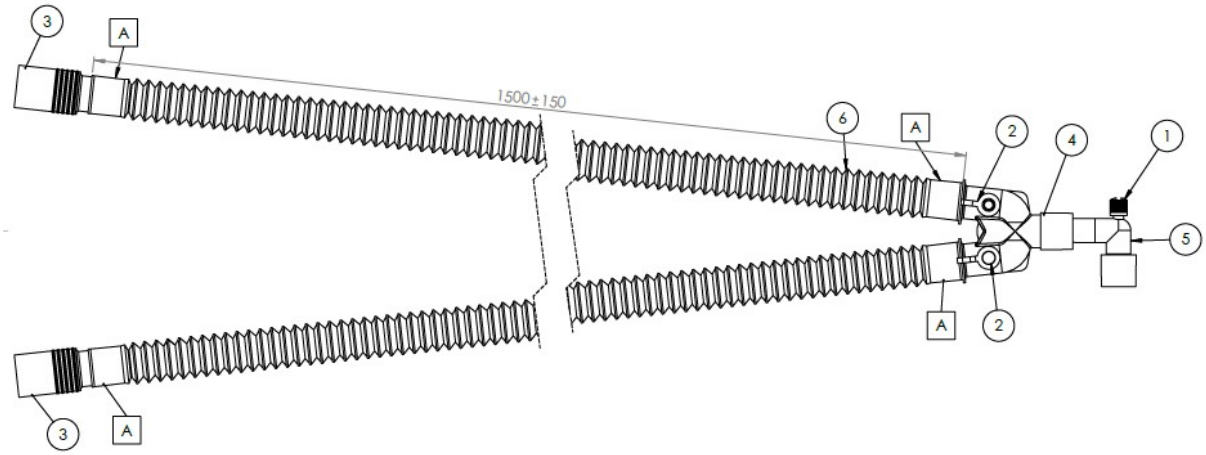

2. MANUFACTURER

Meditera Tıbbi Malzeme Sanayi ve Ticaret A.Ş.

3. INTENDED USE AND FUNCTIONAL DESCRIPTION

Disposable devices used to conduct medical gases from the anaesthesia system to the patient. This product provide heat transfer from expiration to inspiration side helping to reduce the patients energy demands and aiding in their ability to remain norm thermic. Reduced tubing mess supports clinicians' efforts in the delivery of a general anaesthetic.

4. CLASSIFICATION

Class IIa Rule 2

5. PRODUCTION

5.1. Specification of the product :

Code	Description	Quantity
150.11.036	ELBOW CONNECTOR LUER CAP	1,00
151.03.220	22M - 22F STRAIGHT CONNECTOR PP FOR EXTENDIBLE	2,00
151.03.224.01	ELBOW CONNECTOR WITH PORT PP	1,00
151.03.225.01	ANGLED Y CONNECTOR FOR TIGHT FIT WIHT PORT PP	1,00
151.03.264	Y CONNECTOR CAP (NEW)	2,00
151.05.02.203	22 MM EXTENDIBLE TUBING 150 CM CUT (ADFLEXX)	2,00

5. BIOCOMPATIBILITY

This product is biocompatible according to ISO 10993-1.

6. PRODUCTION ENVIROMENT

This product is produced according to the requirements of ISO 13485 and MDD 93/42/EEC in a validated and monitored Class 8 cleanroom according to the EN ISO 14644-1 “Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness”.

7. STERILIZATION

This product can be supplied in non-sterile condition and sterile condition to the customer.

8. SHELF-LIFE AND STORAGE CONDITIONS

The shelf-life of this product is 5 (five) years if the product is stored under normal conditions(room temterature, dry and original packaging). Expiration date is printed on the packaging label.

9. WARNINGS

Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the 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.

Dispose according to hospital guidelines.

10. Applied Standarts:

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