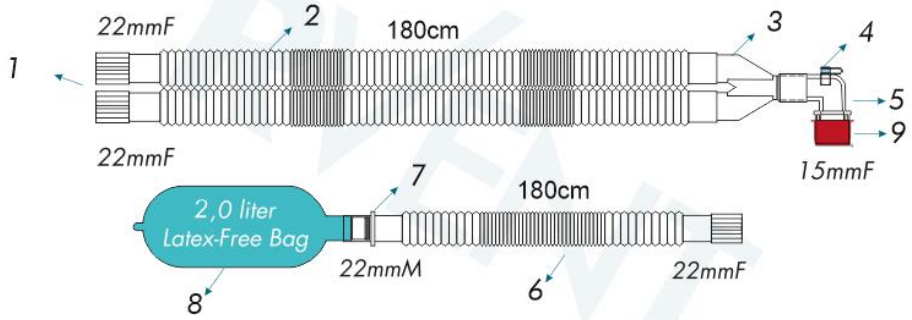
BREATHING CIRCUIT NAME/ REFERENCE NUMBER	Anesthesia Circuit, Adult, Extendible Tubing, Latex-free Bag/31305020-15
MANUFACTURER NAME	R VENT Medikal Uretim A.S. Yazibasi Mah. Balkan Cad. No:33, Torbalı, 35860- Izmir, Turkey Tel: +90 232 853 9500 E-mail: info@rventmedikal.com
REGULATORY APPROVALS AND CERTIFICATION	ISO 13485 – 31816401 CE Certificate – 2195-MED-1816401
CLASSIFICATION	Disposable Medical Device MDD 93/42/EEC Class IIa Rule 2 Annex V, Article 3
GMDN CODE/DESCRIPTION	**37704** **Anaesthesia breathing circuit, single-use** An assembly of devices designed to conduct medical gases from an anaesthesia unit/workstation to a patient artificial airway/anaesthesia mask (not included) during general anaesthesia. It includes breathing tubes and a Y-piece connector, typically with a ventilator/ventilation bag and appropriate connectors, and may include a carbon dioxide (CO2) absorber, a one-way directional valve, or adjustable pressure limiting (APL) valve. This is a single-use device.
EMDN CODE/DESCRIPTION	**R02010101** Breathing Circuits, w/o Water Trap
FEATURES	• Disposable breathing circuits may help reduce cross-contamination. • Available in a wide variety of tubing styles, components and configurations to meet specific needs.
INTENDED USE	Disposable breathing circuit for conduction of respiratory gases between anesthesia machine or ventilator and patient and intended for single use only. Sterile and Non-sterile options are available. Breathing bag with connection hose (limb) intended for use with anesthesia delivery systems as a reservoir during automatic ventilation and as a manual breathing bag during manual ventilation.
TECHNICAL SPECIFICATIONS	**Drawing:**



Materials:

	Components	Materials
1	22M – 22F Straight Connector	Ethylene vinyl acetate (EVA)
2	22 Mm Extendible Tubing 180cm	Polyvinyl Chloride (PVC) (PHT FREE)
3	Y Connector W/Out Port	Polypropylene (PP)
4	Tethered Cap	Low-density polyethylene (LDPE)
5	Elbow Connector with CO2 Port	Polypropylene (PP)
6	22MM Extendible Tubing	Polypropylene (PP)
7	22M-22M/15F Straight Connector	Polypropylene (PP)
8	2lt Breathing Bag	Neoprene
9	Long Connector Red Cap	Ethylene vinyl acetate (EVA)

This product does not contain any metallic parts.

	Appearance: As shown on drawing	
	Recommended Patient: Adult	
	Length of Circuit: 180 cm	
	Connection Port(s): 15mm ID & 22mm OD	
TESTS PERFORMED ON THE PRODUCT	-The Leakage Test -The Pull Test -The Gauge Test -The Routine Assembling And Packaging Process Controls	
APPLICABLE STANDARDS	**Standard Number**	**Standard Name**
	TS EN ISO 5356-1:2015	Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
	TS EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
	TS EN ISO 10993-1:2021	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
	TS EN ISO 10993-5:2010	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
	TS EN ISO 10993-10:2014	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
	TS EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
	TS EN ISO 5362:2019	Anaesthetic reservoir bags
	TS EN ISO 5367:2015	Anaesthetic and respiratory equipment - Breathing sets and connectors
	ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	TS EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	TS EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	TS EN ISO 14644-1:2016	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness
	TS EN ISO 11607-1: 2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
	TS EN ISO 14971:2020	Medical devices - Application of risk management to medical devices
	TS EN ISO 24971:2021	Medical devices — Guidance on the application of ISO 14971
	TS EN ISO 10993-7:2010	Biological evaluation of medical devices part 7: Ethylene oxide sterilization residuals
	TS EN ISO 10993-11: 2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	TS EN ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
	TS EN ISO 11737-2: 2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
	TS EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
STERILIZATION STATUS	Non-sterile	
CLEANING	Device assembled within ISO 8 Cleanroom.	
PRODUCT SHELF LIFE	5 years from the date of manufacturing. Expiration date and date of production are detailed on the product labelling.	
PACKAGING	**Pouch:** Polyethylene (PE) **Box material:** Craft **Box dimention:** 400 mm x 800 mm x 560 mm **Quantity per box:** …	
STORAGE CONDITIONS	Temperature: -20°C to +55°C Humidity: 0% to 95% Luminosity: Keep away from direct sunlight	
TRANSPORTATION CONDITIONS	Temperature: -20°C to +55°C Humidity: 0% to 95%	

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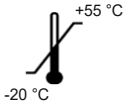
E-mail: info@rventmedikal.com

	Luminosity: Keep away from direct sunlight
PRECAUTIONS	 Keep away from sunlight  Do not use if package is opened or damaged  Do not re-use  Phthalate-free  Consult instruction for use  Latex-free  Do not re sterilize *for sterile products  Storage conditions  Country of manufacture – Date of manufacture  Manufacturer  Sterilized with Ethylene Oxide *for sterile products  CE Marking  Non-sterile *for non sterile products  Lot number  Catalog Number  Expiry Date  Contains Latex *for products made with Latex
WASTE METHOD	Local regulations and/or hospital waste management procedures of the relevant country should be followed when disposing of the used products.
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