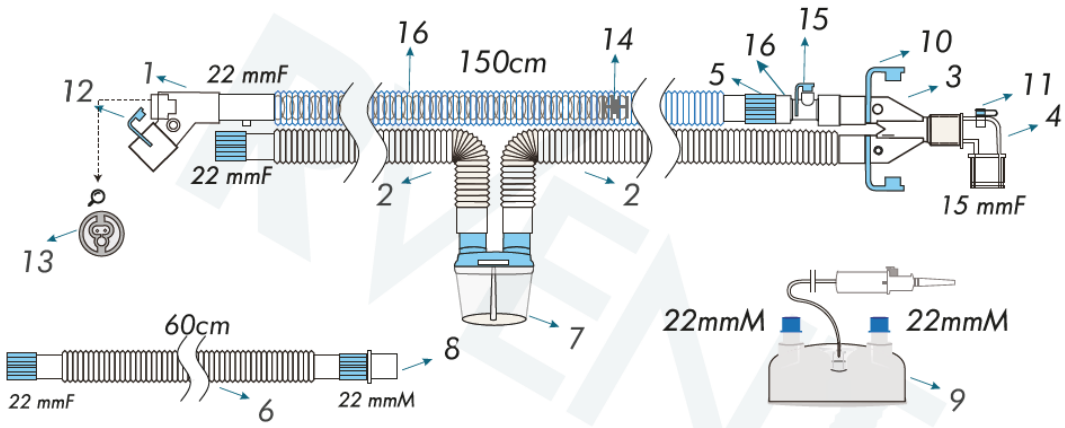

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BREATHING CIRCUIT NAME/REFERENCE NUMBER	Single Heated Wire Circuits, Adult, Corrugated Tubing, Limb, Single Water Trap, /13113001-1																				
MANUFACTURER NAME	R VENT Medikal Uretim A.S. Yazibasi Mah. Balkan Cad. İztipsan Apt. No:33/1, Torbalı, 35860- İzmir, 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	37706 Ventilator breathing circuit, single-use An assembly of devices designed to conduct air or oxygen (O2) enriched gases and additional gases [e.g., nitrous oxide (N2O), halogenated gases] from a ventilator to a patient artificial airway/respiratory mask (not included). It includes breathing tubes, a Y-piece connector, and provides connections for devices that humidify, deliver medication, and monitor gas concentration or pressure within the breathing circuit; some types may include a carbon dioxide cuvette and/or an integrated heating wire powered by a connected humidifier intended to warm breathing gases as they enter the patient's airway. This is a single-use device.																				
EMDN CODE/DESCRIPTION	R02010101 Breathing Circuits, w/out 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 heated wire breathing circuit for conveying moistened breathing gas between the humidifier and patients. Intended for single use only. Sterile and Non-sterile options are available.																				
TECHNICAL SPECIFICATIONS	<p>Drawing:</p>  <p>Materials:</p> <table><thead><tr><th>Components</th><th>Materials</th></tr></thead><tbody><tr><td>1 Angled Elbow Connector 22M-22F with 7.6mm Port</td><td>Polypropylene (PP)</td></tr><tr><td>2 22MM Corrugated Tubing</td><td>Low-density polyethylene (LDPE)</td></tr><tr><td>3 Y Connector with Port</td><td>Polypropylene (PP)</td></tr><tr><td>4 Elbow Connector w/out CO2 Port</td><td>Polypropylene (PP)</td></tr><tr><td>5 22M-22M Straight Connector</td><td>Ethylene vinyl acetate (EVA)</td></tr><tr><td>6 22MM Corrugated Tubing 60 CM</td><td>Low-density polyethylene (LDPE)</td></tr><tr><td>7 22 MM Water Trap</td><td>Poly (methyl methacrylate) (PMMA)</td></tr><tr><td></td><td>Styrene-acrylonitrile (SAN)</td></tr></tbody></table>			Components	Materials	1 Angled Elbow Connector 22M-22F with 7.6mm Port	Polypropylene (PP)	2 22MM Corrugated Tubing	Low-density polyethylene (LDPE)	3 Y Connector with Port	Polypropylene (PP)	4 Elbow Connector w/out CO2 Port	Polypropylene (PP)	5 22M-22M Straight Connector	Ethylene vinyl acetate (EVA)	6 22MM Corrugated Tubing 60 CM	Low-density polyethylene (LDPE)	7 22 MM Water Trap	Poly (methyl methacrylate) (PMMA)		Styrene-acrylonitrile (SAN)
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	8	22M-22M/15F Straight Connector	Polypropylene (PP)
	9	Autofeed Humidifier Chamber	Polypropylene (PP)
			Silicone
			Polyurethane (PU)
			Aluminum
			KR30 + KR90
	10	Y Connector Cap	Ethylene vinyl acetate (EVA)
	11	Tethered Cap	Low-density polyethylene (LDPE)
	12	Y Connector Cap	Ethylene vinyl acetate (EVA)
	13	Adult Heated Wire 16 Ohm Socket	Polypropylene (PP)
	14	Adult Heated Wire Hanger Part	Polypropylene (PP)
	15	Y Connector Cap	Ethylene vinyl acetate (EVA)
	16	22MM Straight Connector With Temperature Port	Polypropylene (PP)
	17	22MM Corrugate Tubing 150cm Cut Blue For	Polypropylene (PP)
		Inspiratory Heated Wire	Ethylene vinyl acetate (EVA)
	This product does not contain any metallic parts.		
	Appearance: As shown on drawing		
	Recommended Patient: Adult		
	Length of Circuit: 150 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	



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	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: 25		
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% Luminosity: Keep away from direct sunlight		
PRECAUTIONS	<div><div></div><div>Keep away from sunlight</div><div></div><div>Sterilized with Ethylene Oxide *for sterile products</div></div> <div><div></div><div>Do not use if package is opened or damaged</div><div></div><div>CE Marking</div></div> <div><div></div><div>Do not re-use</div><div></div><div>Non-sterile *for non sterile products</div></div> <div><div></div><div>Phthalate-free</div><div></div><div>Lot number</div></div> <div><div></div><div>Consult instruction for use</div><div></div><div>Catalog Number</div></div> <div><div></div><div>Latex-free</div><div></div><div>Expiry Date</div></div> <div><div></div><div>Do not re sterilize *for sterile products</div><div></div><div>Contains Latex *for products made with Latex</div></div> <div><div></div><div>Storage conditions +55 °C -20 °C</div></div> <div><div></div><div>Country of manufacture – Date of manufacture</div></div> <div><div></div><div>Manufacturer</div></div>		
WASTE METHOD	Local regulations and/or hospital waste management procedures of the relevant country should be followed when disposing of the used products.		
NOTES	-		

