
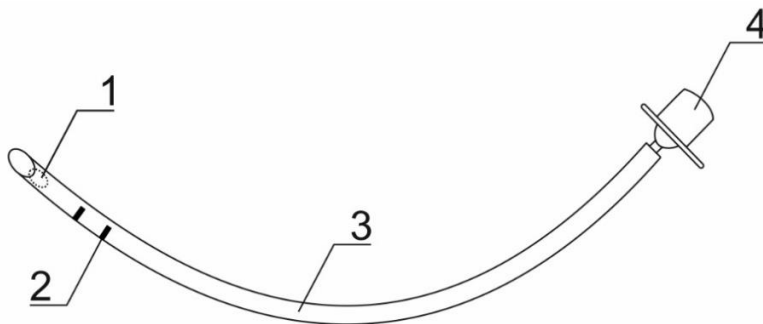
	Technical data sheet		att.no.6 pt.1 subpt.1.1
	Endotracheal tube uncuffed		revision 4
			date: 2021-05-31
	TD-40		amendment of: 2023-11-24

MEDICAL DEVICE DATA			
CATALOGUE NUMBER	RIB-20, RIB-25, RIB-30, RIB-35, RIB-40, RIB-45, RIB-50, RIB-55, RIB-60, RIB-65, RIB-70, RIB-75, RIB-80, RIB-85, RIB-90, RIB-95, RIB-100		
MANUFACTURER	ZARYS International Group sp. z o.o. sp.k. ul. Pod Borem 18, 41-808 Zabrze		
CLASSIFICATION	Ila	RULE	5
METHOD OF STERILIZATION	ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO GMDN	46967
PERFORMANCE CHARACTERISTICS	Device introduced through the nose or mouth into the trachea in order to: - ensuring airway patency - performing artificial ventilation - preventing pulmonary aspiration of gastric contents and enabling its aspiration - administering medicines in cases of sudden cardiac arrest (alternative route) Endotracheal tube is inserted using a laryngoscope.		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	EN ISO 5356-1 Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets EN ISO 5361 Anaesthetic and respiratory equipment - Tracheal tubes and connectors EN ISO 15001 Anaesthetic and respiratory equipment -- Compatibility with oxygen		

TECHNICAL DATA	
RAW MATERIALS	<ul style="list-style-type: none"> <li>tube – medical PVC</li> <li>radiopaque line – BaSO4 (barium sulphate)</li> <li>connector – PP (polypropylene)</li> <li>overprint/ink - Marastar SR</li> </ul>
COLOUR	<ul style="list-style-type: none"> <li>tube – transparent</li> <li>radiopaque line – blue</li> <li>connector – white + transparent</li> <li>overprint/ink - black</li> </ul>
FEATURES	<ul style="list-style-type: none"> <li>made of thermoplastic PVC for high elasticity of the tube</li> <li>X-ray marker over the entire tube length</li> <li>equipped with side Murphy eye</li> <li>tube size marked in 3 places (on the connector and in two places on the tube body)</li> <li>double depth marker to control the position of the tube</li> <li>graduated every 1 cm</li> <li>detachable connector with an outer diameter of 15 mm</li> <li>latex-free</li> <li>contains phthalates</li> <li>single-use</li> <li>EO sterilized</li> <li>individual packaging: paper-foil</li> <li>shelf life – 5 years</li> </ul>
VARIABLES	n/a
EQUIPMENT	n/a
SIZE / VOLUME	I.D. (mm): 2.0; 2.5; 3.0; 3.5; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 7.5; 8.0; 8.5; 9.0; 9.5; 10.0

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TECHNICAL DRAWING							
DESCRIPTION OF PARTS OF THE PRODUCT AND ITS FUNCTON	<div><div>1.</div><div>lateral Murphy eye – alternative route for the breathing mixture in case of closure of the distal opening e.g. by adhesion to the tracheal wall</div></div> <div><div>2.</div><div>depth markers – facilitates verification of the position of the tube in the airway</div></div> <div><div>3.</div><div>tube – transports the respiratory mixture to/from the lungs; has imprints: size indication, purpose, scaling and a radiopaque line on the entire length</div></div> <div><div>4.</div><div>connector – allows the tube to be connected to other medical devices intended to support ventilation</div></div>						
DETAILED DIMENSIONS / SPECIFICATION	REF	size	tube			connector	
			OUTER DIAMETER O.D. (mm) / TOLERANCE	INNER DIAMETER I.D. (mm) / TOLERANCE	LENGTH (mm)	OUTER DIAMETER (mm)	LENGTH (mm)
	RIB-20	2.0	2,9 ± 0,15	2,0 ± 0,15	140 ± 2	15	39
	RIB-25	2.5	3,5 ± 0,15	2,5 ± 0,15	145 ± 2	15	39
	RIB-30	3.0	4,2 ± 0,15	3,0 ± 0,15	165 ± 2	15	39
	RIB-35	3.5	4,9 ± 0,15	3,5 ± 0,15	185 ± 2	15	39
	RIB-40	4.0	5,5 ± 0,15	4,0 ± 0,15	210 ± 2	15	39
	RIB-45	4.5	6,0 ± 0,15	4,5 ± 0,15	225 ± 2	15	39
	RIB-50	5.0	6,7 ± 0,15	5,0 ± 0,15	245 ± 2	15	39
	RIB-55	5.5	7,3 ± 0,15	5,5 ± 0,15	275 ± 2	15	39
	RIB-60	6.0	8,0 ± 0,15	6,0 ± 0,15	285 ± 2	15	39
	RIB-65	6.5	8,7 ± 0,20	6,5 ± 0,20	295 ± 2	15	39
	RIB-70	7.0	9,3 ± 0,20	7,0 ± 0,20	310 ± 2	15	39
	RIB-75	7.5	10,0 ± 0,20	7,5 ± 0,20	315 ± 2	15	39
	RIB-80	8.0	10,7 ± 0,20	8,0 ± 0,20	330 ± 2	15	39
	RIB-85	8.5	11,3 ± 0,20	8,5 ± 0,20	330 ± 2	15	39
	RIB-90	9.0	12,0 ± 0,20	9,0 ± 0,20	330 ± 2	15	39
RIB-95	9.5	12,7 ± 0,20	9,5 ± 0,20	330 ± 2	15	39	
RIB-100	10.0	13,3 ± 0,20	10,0 ± 0,20	330 ± 2	15	39	
PACKAGING			number of pieces		packaging material		packaging dimensions
	individual packaging		1 pc.		foil-paper		350 x 150 mm
	intermediate packaging		20 x 1 pc.		flat cardboard		355 x 155 x 120 mm
	bulk packaging		10 x 20 pcs		corrugated cardboard		620 x 370 x 340 mm
STORAGE CONDITIONS	temperature		5°C - 40°C				
	humidity		30% - 80%				
	other		protect from humidity and sunlight				