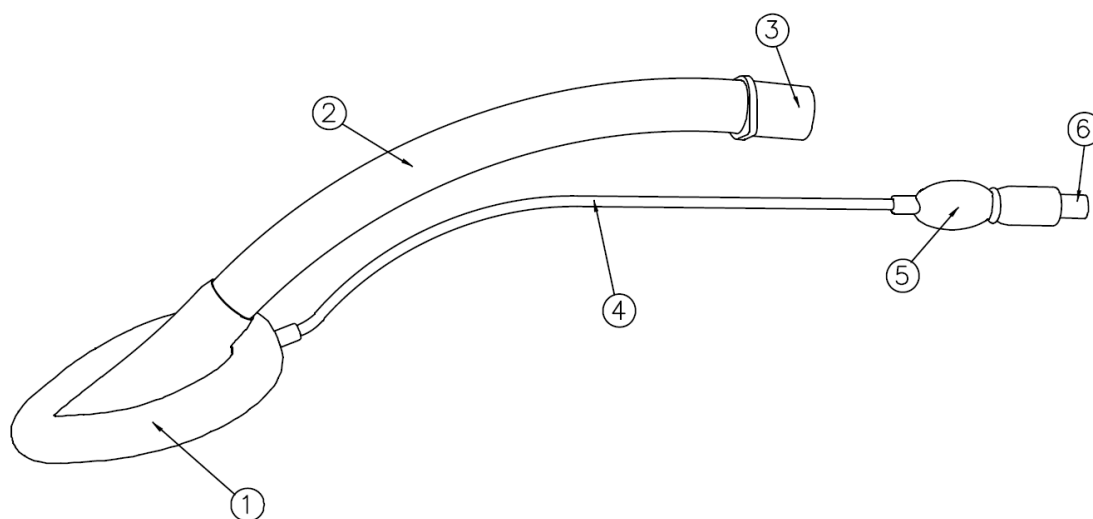
	Technical data sheet	att.no.6 pt.1 subpt.1.1
	TD-40	edition II
	LARYNGEAL MASK, silicone, disposable, sterile	date: 2021-05-31 change of day: 2022-01-11

MEDICAL DEVICE DATA:			
CATALOGUE NUMBER	MKSJ-10, MKSJ-15, MKSJ-20, MKSJ-25, MKSJ-30, MKSJ-40, MKSJ-50		
MANUFACTURER	ZARYS International Group sp. z o.o. sp.k., Poland		
CLASSIFICATION	Ila	RULE	5
METHOD OF STERILIZATION	Ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO UMDNS	45036
PERFORMANCE CHARACTERISTICS	<p>Device inserted through the mouth, up to the back of the throat, forms a seal at the top of the glottis in order to:</p> <ul style="list-style-type: none"> • direct protecting the patient's airway patency • artificial ventilation • maintaining airway patency in: <ul style="list-style-type: none"> - short-term surgical procedures, without the need of muscles relaxation, when endotracheal intubation is not necessary - under anaesthesia for diagnostic procedures - during cardiopulmonary resuscitation, when it is impossible to intubate the patient 		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	EN ISO 5356-1 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets		

TECHNICAL DATA:	
RAW MATERIALS	<ul style="list-style-type: none"> • cuff - silicone • body - silicone • connector - PC (polycarbonate) • connecting tube - silicone • control (pilot) balloon - silicone • valve - PVC
COLOUR	<ul style="list-style-type: none"> • cuff - blue • body - transparent • connector - transparent • connecting tube - transparent • control balloon - colour coding depending on size - information included: DETAILED DIMENSIONS / SPECIFICATIONS • valve - transparent
FEATURES	<ul style="list-style-type: none"> • made from biocompatible silicone for excellent tube flexibility • flexible mask body with detailed description (patient weight, size, cuff volume) • elliptical shape and flexible cuff for safe breath control • universal transparent connector 15 mm • colour-coded control balloon with indication of mask size and cuff volume • colour-coded valve protection facilitates quick identification of size • single-use • latex free • phthalate-free • sterilised by ethylene oxide • foil-paper packaging • shelf life 5 years
VARIABLES	the product is available in 7 sizes; the different mask sizes differ in the colour of the control balloon
SIZE	1; 1,5; 2; 2,5; 3; 4; 5

TECHNICAL DRAWING




DESCRIPTION OF PARTS OF THE PRODUCT AND ITS FUNCTION

1. cuff - after insertion and filling with air, forms a seal at the top of the glottis
2. body - transports the respiratory mixture to/from the lungs
3. connector - enables the laryngeal mask to be connected to other medical devices designed to aid ventilation
4. connection tube - tubing transporting air to seal the cuff
5. control (pilot) balloon - allows control of the degree of filling of the sealing cuff
6. valve - allows filling of the cuff and keeping air in the control balloon as well as deflating it

DETAILED DIMENSIONS / SPECIFICATION

REF		MKSJ-10	MKSJ-15	MKSJ-20	MKSJ-25	MKSJ-30	MKSJ-40	MKSJ-50	tolerance
SIZE		1,0	1,5	2,0	2,5	3,00	4,0	5,0	-
body	INSIDE DIAMETER I.D. (mm)	5,0	6,1	7,0	8,4	10,0	10,0	11,0	± 0,5
	OUTSIDE DIAMETER O.D. (mm)	8,0	10,0	11,2	13,2	15,2	15,2	16,7	± 0,5
	LENGTH (mm)	85	95	120	130	175	175	195	± 5,5
CUFF	LENGTH (mm)	42	48	58	63	78	88	102	± 0,5
	WIDTH (mm)	26	30	36	39	50	56	64	± 0,5
	MAXIMUM VOLUME (ml)	4	7	10	14	20	30	40	-
	MAXIMUM PRESSURE (cm H ₂ O)	< 60	< 60	< 60	< 60	< 60	< 60	< 60	-
PATIENT WEIGHT RANGE (kg)		≤ 5	5-10	12-20	20-30	30-50	50-70	70-100	-
CONTROL BALLOON (colour)		black	white	red	orange	green	yellow	pink	-

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PACKAGING		Number of pieces	Packaging material	Packaging dimensions
	Individual packaging	1 pc.	foli-paper	400 x 150 mm
	Intermediate packaging	5 x 1 pc.	carton	390 x 165 x 85 mm
	Bulk packaging	10 x 5 pcs	corrugated cardboard	445 x 405 x 350 mm
STORAGE CONDITIONS	Temperature	-10°C - 40°C		
	Humidity	0% - 75%		