

# endotracheal tube holder

sterile

## features

- made of high-quality materials
- universal Velcro fasteners enabling fast and effective fixing of the holder around the head
- adjustable handle allows for easy and fast fixation of every size of endotracheal tube
- special design of the bite-piece prevents patient trauma or damaging the tube (by biting)
- additional opening allows for chyme, saliva and blood suction from the oral cavity
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- to stabilize the position of the endotracheal tube after its insertion into the trachea

REF	version	colour
SRI-N	horizontal fixation	blue-red
SRI-A	vertical fixation	green



bulk packaging:  
100 x 1 pc.



# tracheostomy tube

cuffed, sterile

## features

- made of medical, flexible PVC
- swivel 15 mm connector
- flexible neckplates with slits for strap insertion to secure tube position
- soft, low-pressure, thin-walled cuff
- pilot balloon in contrasting colour clearly indicates the level of the cuff's inflation
- 2 fixation straps protected with foil
- clear size marking on the neckplates
- atraumatic, soft rounded tip, curved cannula
- radiopaque line
- equipped with obturator
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./rigid blister

## indication

- to control respiratory tracts in people after tracheostomy
- introduced to the airways by a surgical incision of the tracheal's front wall to allow ventilation
- provides free breathing bypassing the nose, throat and larynx

REF	size	intermediate packaging
RTM-40	4.0	10 pcs
RTM-45	4.5	10 pcs
RTM-50	5.0	10 pcs
RTM-60	6.0	10 pcs
RTM-65	6.5	10 pcs
RTM-70	7.0	10 pcs
RTM-75	7.5	10 pcs
RTM-80	8.0	10 pcs
RTM-85	8.5	10 pcs
RTM-90	9.0	10 pcs
RTM-95	9.5	10 pcs
RTM-100	10.0	10 pcs



bulk packaging:  
10 x 10 pcs



# dual-limb breathing circuit

sterile

## features

- made of high quality EVA material, without PVC
- 15F/22M and 22F universal connector fits compatible products and devices for mechanical ventilation or anesthesia machine
- expandable arms with maximum length of 160 cm
- adjustable length of circuit enabling adjustment of length of respiratory system and optimization of dead space
- equipped with latex-free breathing bag: 3l (for adults) or 1l (for children)
- additional expandable tube, length: 100 cm
- elbow with luer lock port
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

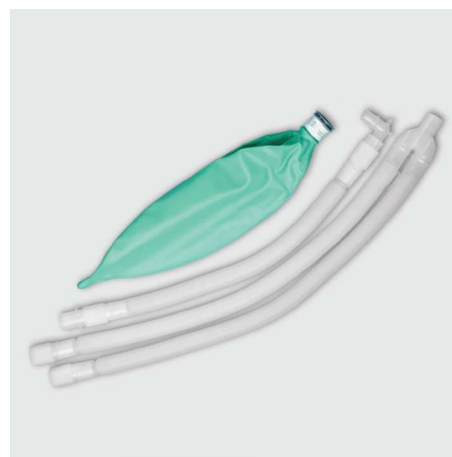
## indication

- for patient's mechanical ventilation
- it enables transporting breathing mixture from equipment (ventilator, anesthesia machine) to respiratory protection device (e.g. tracheal tube, tracheostomy mask) and vice versa

REF	purpose	capacity of bag
OBWD-1601L	for children	1 liter
OBWD-1603L	for adults	3 liters



bulk packaging:  
40 x 1 pc.



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# catheter mount/double swivel connector

sterile

## features

- standard version made of medical PVC
- expandable version made of high quality EVA material, PVC-free and phthalate-free
- 22M/15F - 15M universal connector fits compatible products
- expandable version characterized by shape memorizing and by the ability to control the position of the connector
- double swivel elbow connector
- port for suctioning and bronchoscope secured with a stopper
- available in versions: standard and expandable
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- used to connect the tracheostomy tube or endotracheal tube with the breathing circuit of the ventilation device
- provides greater mobility and rotation of the connection, increasing patient comfort and safety

REF	version	length
PM-15	standard	15 cm
PMR-15	expandable	9-18 cm



bulk packaging:  
250 x 1 pc.



**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60139535 0001

**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

**Products:** (see attachments for products and sites included)  
Replaces EC Certificate, Registration No.: DD 60117020 0001

**Expiry Date:** 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-06-09

**Date:** 2019-05-27

Notified Body

Rafal Byczkowski



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/6, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** DD 60139535 0001  
**Report No.:** 26300232 017

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs  
(with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges  
(with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls  
(with or without X-ray thread)
- Sterile and non-sterile gauze rolls  
(with or without X-ray thread)
- Sterile and non-sterile non-woven swabs  
(with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

**Notified Body**



**Rafal Byczkowski**



**Date: 2019-05-27**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/6, Rev. 0

**Attachment to  
Certificate**

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Spolka z ograniczona odpowiedzialnoscia,  
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41-808 Zabrze  
Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

**Date: 2019-05-27**

**Notified Body**

  
**Rafal Byczkowski**



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41-808 Zabrze  
Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

**Date:** 2019-05-27

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41-808 Zabrze  
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

Notified Body



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41-808 Zabrze  
Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Notified Body



**Date: 2019-05-27**

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spolka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Polska

Products included:

ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Gustawa Eiffel'a 15  
44-109 Gliwice  
Poland

Activity: Production

**Date: 2019-05-27**

**Notified Body**

**Rafal Byczkowski**



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1023663-1

Organization: ZARYS International Group  
Spółka z ograniczoną odpowiedzialnością,  
spółka komandytowa  
ul. Pod Borem 18  
41-808 Zabrze  
Poland

Scope: Design and development, manufacture and distribution of sterile:  
surgical kits, procedure sets, surgical drapes and sets of surgical  
drapes.  
Manufacture and distribution of sterile and non-sterile disposable  
medical devices and non-sterile reusable medical devices.  
Distribution of in-vitro medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the above mentioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10



Rafał Byczkowski  
TR LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany