

## BEN medical cap with ties

### features:

- forage cap with ties at the back
- made of perforated Spunlace Mesh non-woven
- excellent breathability and comfort of use
- single-use, non-sterile



116

REF	packaging unit
BT-007-35B-SPNM	100 pcs



bulk packaging:  
10 x 100 pcs



available colours:



## TOM medical cap with ties

### features:

- cap with ties at the back
- anti-sweat insert on the whole circumference
- made of polypropylene non-woven 20 g/m<sup>2</sup>
- packaging: ergonomic cardboard box to remove individual pieces
- single-use, non-sterile



REF	packaging unit
BT-007-P20G	100 pcs



bulk packaging:  
10 x 100 pcs



anti-sweat  
insert



available colours:



## ROS medical cap with ties

### features:

- cap with ties at the back
- anti-sweat insert in the forehead area
- made of Spunlace and polypropylene non-woven
- packaging: ergonomic cardboard box to remove individual pieces
- latex-free
- single-use, non-sterile



REF	packaging unit
BT-007-P45B	50 pcs



bulk packaging:  
6 x 50 pcs



anti-sweat  
insert



available colours:



## nasal oxygen cannula

sterile

### features

- made of medical PVC
- very soft tips with smooth edges
- fastening under the chin with a soft, sliding adjustment ring
- various spacing of the nasal part of the cannula depending on the size
- universal connector compatible with any source of oxygen
- tubing with star cross-section that is resistant to bending
- available in 3 sizes: for adults, for children and for infants with 140 cm, 200 cm, 300 cm and 500 cm long tubing
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./foil

### indication

- designed to deliver oxygen through the nose

REF	length of tubing	purpose	intermediate packaging	bulk packaging
CTNN-200	200 cm	for infants	25 pcs	10 x 25 pcs
CTNZ-200	200 cm	for children	25 pcs	10 x 25 pcs
CTND-140	140 cm	for adults	30 pcs	10 x 30 pcs
CTND-200	200 cm	for adults	25 pcs	10 x 25 pcs
CTND-300	300 cm	for adults	15 pcs	10 x 15 pcs
CTND-500	500 cm	for adults	10 pcs	10 x 10 pcs



## oxygen tubing

sterile

### features

- made of transparent, non-toxic PVC
- tubing with star cross-section that is resistant to bending, with reinforcing straps along the entire length
- standardized connectors at the end of the tubing allowing connection to oxygen devices
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

### indication

- for transporting oxygen from an oxygen source to another medical device for oxygen supply, e.g. oxygen mask

REF	length of tubing	bulk packaging
DT2100	210 cm +/- 2%	100 x 1 pc.
DT4260	426 cm +/- 2%	50 x 1 pc.
DT7620	762 cm +/- 2%	25 x 1 pc.



## EYE DRESSINGS

### features

- layered structure: non-woven + cellulose pulp
- needs to be fixed with a secondary dressing e.g. with adhesive tape or tubular net bandage
- hypoallergenic

### indication

- covering an eye and its area after ophthalmic procedures and surgical procedures
- sight correction in strabismus therapy



### eye pad

#### elastoLUMENAL



non-sterile

Before use on open wounds, the device must be sterilized in accordance with a validated sterilization method. It can be sterilized with ethylene oxide or radiation.

REF	dimensions	packaging unit paper-paper	intermediate packaging box	bulk packaging carton
803311	5 cm x 7,5 cm	1 pc.	50 x pc.	24 x pcs



#### elastoLUMENAL S



sterile

REF	dimensions	packaging unit paper-paper	intermediate packaging box	bulk packaging carton
803310	5, cm x 7,5 cm	1 pc.	50 x 1 pc.	24 x 50 pcs

Conforms well to facial contours thanks to the oval shape.

## SELF-ADHESIVE DRESSINGS WITH ABSORBENT PAD

### features

- self-adhesive dressings with centrally situated absorbent pad, made of hydrophobic non-woven, covered with acrylic glue
- absorbent pad coated with a polyethylene mesh that prevents sticking to the wound, absorbs a small and medium amount of exudate and protects against the influence of external factors
- rounded edges prevent accidental removal of the dressing
- silicone backing paper facilitates the precise, painless and efficient application
- micropores in the structure of the non-woven provide adequate vapor permeability, thanks to which a proper gas exchange between the dressing and the skin takes place
- hypoallergenic

88



made of hydrophobic non-woven



air permeable structure



white colour



BESTSELLER

### non-woven dressing with absorbent pad

#### elastopor STERIL



sterile

#### indication

- especially recommended for covering surgical wounds
- for treating wounds with a small and medium amount of exudate

REF	dimensions	packaging unit paper-paper	bulk packaging box
801001	5 cm x 7,2 cm	1 pc.	100 x 1 pc.
801012	6 cm x 10 cm	1 pc.	50 x 1 pc.
801002	8 cm x 10 cm	1 pc.	30 x 1 pc.
801013	10 cm x 10 cm	1 pc.	30 x 1 pc.
801021	10 cm x 12 cm	1 pc.	30 x 1 pc.
801014	10 cm x 15 cm	1 pc.	30 x 1 pc.
801003	6 cm x 15 cm	1 pc.	50 x 1 pc.
801004	8 cm x 15 cm	1 pc.	30 x 1 pc.
801005	8 cm x 20 cm	1 pc.	30 x 1 pc.
801015	10 cm x 20 cm	1 pc.	25 x 1 pc.
801016	10 cm x 25 cm	1 pc.	25 x 1 pc.
801017	10 cm x 30 cm	1 pc.	25 x 1 pc.
801018	10 cm x 35 cm	1 pc.	25 x 1 pc.



made of hydrophobic non-woven



air permeable structure



white colour

### non-woven dressing with absorbent pad, incision and O-hole

#### elastopor STERIL D



sterile

#### indication

- dressing application around the inserted drain
- securing the outlet of drains and catheters
- for treating wounds with a small and medium amount of exudate

REF	dimensions	packaging unit paper-paper	bulk packaging box
801031	9 cm x 10 cm	1 pc.	30 x 1 pc.
801030	12 cm x 14 cm	1 pc.	25 x 1 pc.

## oxygen mask

### with tubing, sterile

#### features

- made of transparent, non-toxic PVC
- adjustable nose metal plate and rubber fastening
- equipped with a 210 cm (+/- 5%) long tubing with universal connectors
- tubing with star cross-section that is resistant to bending
- revolving connector that allows adjusting to patient's position
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

#### indication

- designed to deliver oxygen with precise regulation of concentration, for medium oxygen concentration

REF	length of tubing	size
MTS-S	210 cm +/- 5%	S
MTS-M	210 cm +/- 5%	M
MTS-L	210 cm +/- 5%	L
MTS-XL	210 cm +/- 5%	XL



bulk packaging:  
50 x 1 pc.



## non-rebreather mask

### with tubing, sterile

#### features

- made of transparent, non-toxic PVC
- adjustable nose metal plate and rubber fastening
- equipped with a 210 cm (+/- 5%) long tubing with universal connectors
- tubing with star cross-section that is resistant to bending
- 1000 ml oxygen reservoir
- revolving connector that allows adjusting to patient's position
- silicone valves on the connector and ventilation openings
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

#### indication

- designed to deliver oxygen with precise regulation of concentration, for high oxygen concentration

REF	length of tubing	size
MTW-S	210 cm +/- 5%	S
MTW-M	210 cm +/- 5%	M
MTW-L	210 cm +/- 5%	L
MTW-XL	210 cm +/- 5%	XL



bulk packaging:  
50 x 1 pc.



## dicoNEX

### single-use syringe, 3-part, luer, sterile

#### features

- transparent barrel allows full visual control of content
- green contrasting plunger
- luer nozzle
- sealing in the form of double ring on plunger stopper situated on the top of plunger
- smooth plunger sliding thanks to rubber sealing
- limitation flange securing against accidental removal of plunger
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage, adequately:
  - every 0,1 ml for capacity of 2 ml
  - every 0,2 ml for capacity of 5 ml
  - every 0,2 ml for capacity of 10 ml
  - every 0,5 ml for capacity of 20 ml
  - every 1 ml for capacity of 50 ml
- single-use, non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

#### indication

- 3-piece syringe intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient

REF	capacity	intermediate packaging	bulk packaging
002ML-3CZ-BL	2 ml	100 pcs	30 x 100 pcs
005ML-3CZ-BL	5 ml	100 pcs	24 x 100 pcs
010ML-3CZ-BL	10 ml	100 pcs	16 x 100 pcs
020ML-3CZ-BL	20 ml	50 pcs	16 x 50 pcs
050ML-3CZ-BL	50 ml	25 pcs	16 x 25 pcs



## dicoNEX

### single-use syringe, 3-part, luer lock, sterile

#### features

- transparent barrel allows full visual control of content
- green contrasting plunger (amber-coloured syringe - white contrasting plunger)
- luer lock nozzle
- sealing in the form of double ring on plunger stopper situated on the top of plunger
- smooth plunger sliding thanks to rubber sealing
- limitation flange securing against accidental removal of plunger
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage, adequately:
  - every 0,1 ml for capacity of 2 ml
  - every 0,2 ml for capacity of 5 ml and of 10 ml
  - every 0,5 ml for capacity of 20 ml
  - every 1 ml for capacity of 30 ml and of 50 ml
- single-use
- non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

#### indication

- 3-piece syringe intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient
- amber-coloured syringe is intended for drawing up and administering of photosensitive medicines

REF	capacity	colour of plunger	intermediate packaging	bulk packaging
003ML-3CZ-LL-BL	3 ml	green	100 pcs	30 x 100 pcs
005ML-3CZ-LL-BL	5 ml	green	100 pcs	24 x 100 pcs
010ML-3CZ-LL-BL	10 ml	green	100 pcs	16 x 100 pcs
020ML-3CZ-LL-BL	20 ml	green	50 pcs	16 x 50 pcs
030ML-3CZ-LL-BL	30 ml	green	50 pcs	16 x 50 pcs
050ML-3CZ-LL-BL	50 ml	green	25 pcs	16 x 25 pcs

#### amber type

050ML-3CZ-LL-B-BL	50 ml	white	25 pcs	16 x 25 pcs
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# endotracheal tube

cuffed, sterile

## features

- made of flexible PVC
- equipped with lateral Murphy eye and radiopaque line over the entire tube length
- graduated every 1 cm, double depth marker to control the position of the tube
- low-pressure, high-volume cuff
- tube size marked in 4 places (on the connector, on the pilot balloon and in two places on the tube body)
- detachable connector with an outer diameter of 15 mm
- pilot balloon with LOT and size indication
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- for both oral and nasal intubation
- inserted into the trachea to prevent airway obstruction and respiratory failure

REF	size	intermediate packaging
RIM-30	I.D. (mm) 3.0	20 pcs
RIM-35	I.D. (mm) 3.5	20 pcs
RIM-40	I.D. (mm) 4.0	20 pcs
RIM-45	I.D. (mm) 4.5	20 pcs
RIM-50	I.D. (mm) 5.0	20 pcs
RIM-55	I.D. (mm) 5.5	20 pcs
RIM-60	I.D. (mm) 6.0	20 pcs
RIM-65	I.D. (mm) 6.5	20 pcs
RIM-70	I.D. (mm) 7.0	20 pcs
RIM-75	I.D. (mm) 7.5	20 pcs
RIM-80	I.D. (mm) 8.0	20 pcs
RIM-85	I.D. (mm) 8.5	20 pcs
RIM-90	I.D. (mm) 9.0	20 pcs
RIM-95	I.D. (mm) 9.5	20 pcs
RIM-100	I.D. (mm) 10.0	20 pcs



bulk packaging:  
10 x 20 pcs



# reinforced endotracheal tube

cuffed, sterile

## features

- made of flexible PVC
- reinforcing within the wall of the entire tube
- equipped with lateral Murphy eye and radiopaque line over the entire tube length
- graduated every 1 cm, double depth marker to control the position of the tube
- tube size marked in 4 places (on the connector, on the pilot balloon and in two places on the tube body)
- detachable connector with an outer diameter of 15 mm
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- for both oral and nasal intubation
- inserted into the trachea to prevent airway obstruction and respiratory failure
- for intubation of the patient in an unusual position, with a high risk of kinking the endotracheal tube

REF	size	intermediate packaging
RIMZP-30	I.D. (mm) 3.0	10 pcs
RIMZP-35	I.D. (mm) 3.5	10 pcs
RIMZP-40	I.D. (mm) 4.0	10 pcs
RIMZP-45	I.D. (mm) 4.5	10 pcs
RIMZP-50	I.D. (mm) 5.0	10 pcs
RIMZP-55	I.D. (mm) 5.5	10 pcs
RIMZP-60	I.D. (mm) 6.0	10 pcs
RIMZP-65	I.D. (mm) 6.5	10 pcs
RIMZP-70	I.D. (mm) 7.0	10 pcs
RIMZP-75	I.D. (mm) 7.5	10 pcs
RIMZP-80	I.D. (mm) 8.0	10 pcs
RIMZP-85	I.D. (mm) 8.5	10 pcs
RIMZP-90	I.D. (mm) 9.0	10 pcs
RIMZP-95	I.D. (mm) 9.5	10 pcs
RIMZP-100	I.D. (mm) 10.0	10 pcs



bulk packaging:  
10 x 10 pcs



## 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



**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**



**Date: 2019-05-27**

  
**Rafal Byczkowski**

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

Doc. 2/6, 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 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**



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

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Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
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

**Notified Body**

  
**Rafal Byczkowski**



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

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spolka komandytowa  
ul. Pod Borem 18  
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**



**Date: 2019-05-27**

  
**Rafal Byczkowski**

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

**Attachment to  
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**Manufacturer:** ZARYS International Group  
Spolka z ograniczona odpowiedzialnoscia,  
spolka komandytowa  
ul. Pod Borem 18  
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**

**Rafal Byczkowski**

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

**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:

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