

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

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/m²
- 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.



nebulizer

with mouthpiece and tubing, sterile

features

- made of transparent, non-toxic PVC
- tubing with star cross-section that is resistant to bending
- 15 ml nebulizer (graduated at 2, 4, 6, 9, 12, 15 ml)
- set components: nebulizer, tubing, mouthpiece
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./foil

indication

- designed for producing aerosol containing a comminuted medicine, that can be delivered directly to the respiratory system as the patient breathes

REF	length of tubing	bulk packaging:
NUD	210 cm +/- 5%	50 x 1 pc.





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

elastopor STERIL D



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.

made of
hydrophobic
non-woven

air permeable
structure

white
colour



non-woven eye dressing with absorbent pad

elastopor EYE



indication

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

REF	dimensions	shape	colour	packaging unit paper-paper	bulk packaging box
803010	5,8 cm x 8,3 cm		absorbent pad - white	1 pc.	50 x 1 pc.
803011	6,5 cm x 9,4 cm		non-woven material - white	1 pc.	50 x 1 pc.
803212	5 cm x 7,5 cm		absorbent pad - white non-woven material - beige colour	1 pc.	50 x 1 pc.

Conforms well to facial contours thanks to the oval shape.

white or skin
colour



HOW TO CHOOSE A DRESSING PROPERLY?

When choosing the proper type of dressing, pay special attention to:

- absorption rate and absorption capacity,
- vapor permeability,
- possibility of an atraumatic dressing change,
- safety of use.

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 catheter syringe, 3-part, sterile

features

- transparent barrel allows full visual control of content
- green contrasting plunger
- two luer connectors attached
- 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
- nozzle cut at 90°
- catheter nozzle secured with cap
- name of syringe and manufacturer's logo placed on barrel
- extended graduation
- clear, legible and permanent black graduation facilitating dosage
- graduated every 1 ml
- single-use
- non-pyrogenic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

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

REF	type	capacity	position of nozzle	intermediate packaging
050ML-3CZ-CEW-BL	catheter tip	50/60 ml	centric	25 pcs



bulk packaging:
16 x 25 pcs



dicoNEX

single-use catheter syringe, 3-part, sterile

features

- 3-piece syringe with centrally located nozzle for catheter
- two luer connectors attached
- made of polypropylene
- transparent barrel allows full visual control of content
- white contrasting plunger
- 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
- nozzle cut at 45°
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage
- graduated every 2 ml
- latex-free, phthalate-free
- single-use
- EO sterilized
- packaging: 1 pc./paper-foil

indication

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

REF	type	capacity	position of nozzle	intermediate packaging
100ML-3CZ-CEW-BL	catheter tip	100 ml	centric	25 pcs



bulk packaging:
4 x 25 pcs



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)
- indissociable 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

Notified Body



Rafal Byczkowski



Date: 2019-05-27

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/6, Rev. 0

**Attachment to
Certificate**

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

Manufacturer: ZARYS International Group
Spolka z ograniczoną odpowiedzialnością,
spółka 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

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/6, 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:

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

Doc. 5/6, 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:

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

Date: 2019-05-27

Notified Body

Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 6/6, 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:

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

Activity: Production

Notified Body

Date: 2019-05-27


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

1 / 2