

## SHOE COVERS

non-sterile

### features:

- made of polyethylene or polypropylene non-woven 30 g/m<sup>2</sup> or 40 g/m<sup>2</sup> (for shoe covers with anti-skid layer)
- elastic rubber band at the opening
- protection against contaminating rooms where higher cleanliness standards are required
- increased durability
- single-use

REF	material	grammage	size	colour	packaging unit
BT-010-G	non-woven	30 g/m <sup>2</sup>	38 cm x 17 cm	green	100 pcs
BT-010-B	non-woven	30 g/m <sup>2</sup>	38 cm x 17 cm	blue	100 pcs
BT-011-B	non-woven with anti-skid layer	40 g/m <sup>2</sup>	38 cm x 17 cm	blue	100 pcs
BT-002-PEB	polyethylene		41 cm x 15 cm	blue	100 pcs

available colours:



**BESTSELLER**



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## SHOE COVERS

calf-high, non-sterile

### features:

- made of polypropylene non-woven 30 g/m<sup>2</sup>
- elastic rubber band at the opening
- protection against contaminating rooms where higher cleanliness standards are required
- increased durability
- single-use

REF	material	grammage	size	packaging unit
BT-013-B	PP non-woven	30 g/m <sup>2</sup>	47 cm x 38,5 cm	100 pcs

available colours:



## DISPOSABLE SLIPPERS

non-sterile

### features:

- made of polypropylene non-woven 90 + 30 g/m<sup>2</sup>
- dimensions: approx. 28 cm x 12 cm
- single-use

REF	packaging unit
BT-003-W	50 pairs

**bulk packaging:**  
10 x 50 pairs

available colours:



## medical bouffant cap, non-woven

### features:

- cap with an elastic rubber band
- diameter: approx. 53 cm
- made of airy polypropylene non-woven
- excellent breathability and wearing comfort
- packaging: ergonomic cardboard box to remove individual pieces
- single-use, non-sterile

REF	colour	packaging unit
BT-008-18G	green	100 pcs
BT-008-18B	blue	100 pcs



bulk packaging:  
10 x 100 pcs



available colours:



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## DONA medical bouffant cap

### features

- cap with an elastic rubber band
- diameter: approx. 47 cm
- made of perforated viscose non-woven
- excellent breathability and wearing comfort
- packaging: ergonomic cardboard box to remove individual pieces
- single-use, non-sterile

REF	colour	packaging unit
BT-008-25G-B1-V	green	100 pcs
BT-008-25B-B1-V	blue	100 pcs
BT-008-25G-B1-V-XL	green	100 pcs



bulk packaging:  
4 x 100 pcs



available colours:



## LILI medical cap with rubber

### features:

- cap with an elastic rubber band in the back part
- made of perforated viscose non-woven
- excellent breathability and wearing comfort
- packaging: ergonomic cardboard box to remove individual pieces
- single-use, non-sterile

REF	colour	packaging unit
BT-001-25G-R1-V	green	100 pcs
BT-001-25B-R1-V	blue	100 pcs
BT-001-25P-R1-V	pink	100 pcs
BT-001-25Y-R1-V	yellow	100 pcs



bulk packaging:  
6 x 100 pcs



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.



## 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.



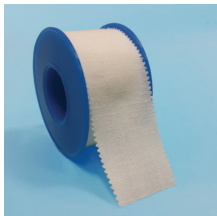
## ADHESIVE TAPES

### features

- flexible, conforms to the body's contours, guarantees freedom of movement
- characterized by adequate air and water vapour permeability
- good adhesion
- can be divided lengthwise and widthwise without the use of scissors
- hypoallergenic

### indication

- stabilization, protection and fixation of primary, non-adhesive dressings, applied directly to wounds and skin damages
- stabilization, protection and fixation of drains, catheters, medical tubes that do not require specialized fixing in the place of their insertion



### adhesive fabric tape, white

#### SENSIplast

 non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
STA12505W	1,25 cm x 5 m	24 pcs	30 x pcs
STA25005W	2, cm x 5 m	12 pcs	30 x 12 pcs
STA50005W	5 cm x 5 m	pcs	30 x 6 pcs
STA12509W	1,25 cm x 9,14 m	24 pcs	30 x 24 pcs
STA25009W	2,5 cm x 9,14 m	12 pcs	30 x 12 pcs
STA50009W	cm x 9,14 m	6 pcs	30 x pcs

  
made of cotton fabric

  
serrated edge

  
spooled

  
white colour



### adhesive fabric tape, skin colour

#### PLASTIplast

 non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
SZO12505S	1,25 cm x 5 m	24 pcs	30 x 24 pcs
SZO25005S	2,5 cm x 5 m	12 pcs	30 x 12 pcs
SZO50005S	5 cm x 5 m	6 pcs	30 x 6 pcs

  
made of cotton fabric

  
serrated edge

  
on a roll

  
skin colour

**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**

**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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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**



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**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:

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**  
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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:

- 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 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