

PERSONAL PROTECTIVE EQUIPMENTS pp.132-133

BETASAFE

133 | protective coverall **SAFE +** against chemical and infective agents type 4b-5b-6b

SURGICAL SETS, DRAPES AND GOWNS pp.134-187

SURGICAL DRAPES

2-layer surgical drapes

- 141 sterile surgical drapes with cellulose layer
- 141 sterile surgical drapes
- 141 sterile surgical drapes with adhesive edge
- 142 sterile surgical drapes with adhesive edge
- 142 sterile surgical drapes with central fenestration
- 142 sterile surgical drapes with adhesive central fenestration
- 143 sterile surgical drapes with adhesive central adjustable fenestration
- 143 sterile adhesive epidural drapes
- 143 sterile instrument table covers

3-layer surgical drapes

- 144 sterile surgical drapes
- 144 sterile surgical drapes with adhesive edge
- 144 sterile surgical drapes with central fenestration
- 145 sterile surgical drapes with adhesive central fenestration
- 145 sterile surgical drapes with adhesive fenestration, reinforced

specialistic surgical drapes

- 146 abdominal drape 1-IF
- 146 abdo-perineal drape 1
- 146 laparoscopy drape 3
- 147 orthopaedic drape 1
- 147 orthopaedic drape 2
- 147 orthopaedic drape 3
- 147 orthopaedic drape 4
- 148 extremity drape 1
- 148 extremity drape 2
- 148 extremity drape 3
- 148 extremity drape 4
- 149 extremity drape 5
- 149 gynaecology drape 1
- 149 gynaecology drape 2
- 149 delivery drape 1
- 150 ophthalmic drape 1-IF
- 150 ophthalmic drape 2-IF
- 150 ophthalmic drape 3-IF
- 150 ophthalmic drape 4-IF

surgical covers

- 152 sterile mayo stand cover, reinforced - red **BESTSELLER!**
- 152 sterile set of limb covers
- 152 sterile limb covers
- 152 sterile camera cabls covers - perforated, with 2 adhesive tapes **BESTSELLER!**
- 152 sterile camera cable cover - unperforated, without adhesive tape

- 153 sterile camera cable cover - unperforated, with an adhesive tape
- 153 sterile circular banded covers for medical devices
- 153 sterile rectangular banded covers for medical devices
- 153 sterile c-arm cover set
- 153 sterile armboard cover set

accessories

- 154 sterile surgical tapes
- 154 sterile adhesive pouches
- 154 sterile adhesive fluid collection pouch
- 154 sterile absorbent drape
- 155 sterile absorbent drape
- 155 sterile incise film **elastoFILM**

SURGICAL SETS

universal sets

- 157 basic set 1
- 157 universal set 1
- 157 universal set 2
- 157 universal set 4 **BESTSELLER!**
- 158 universal set 5 **BESTSELLER!**
- 158 universal set 6
- 158 universal set 7
- 159 universal set 8
- 159 paediatric universal set 9
- 159 universal set 10
- 160 universal set 5-G
- 160 universal set 5-GP

general surgery

- 161 abdominal set 1-IF
- 161 abdo-perineal set 1
- 162 laparoscopy set 1-IF
- 162 laparoscopy set 2 **BESTSELLER!**
- 163 laparoscopy set 3
- 163 varicose vein set 1
- 163 varicose vein set 2

orthopaedics and traumatology

- 164 extremity set 1
- 164 extremity set 2
- 165 arthroscopy set 1
- 165 arthroscopy set 2
- 166 arthroscopy set 2-IP
- 166 arthroscopy set 3
- 167 arthroscopy set 4
- 167 arthroscopy set 5
- 168 hip set 1
- 168 hip set 2
- 169 hip set 3
- 169 shoulder set 1
- 170 shoulder set 2

gynaecology and urology

- 171 gynaecology set 1
- 171 gynaecology set 2 **BESTSELLER!**
- 172 gynaecology set 3
- 172 cystoscopy set 1
- 172 uro/gynaecology set 2
- 173 uro/gynaecology set 3
- 173 tur set 1
- 173 tur set 1 P1 **NEW!**
- 174 percutaneous lithotripsy set 1-IP

obstetrics

- 174 c-section set 1
- 175 c-section set 1-IF
- 175 c-section set 2-IF
- 176 c-section set 3-IF
- 176 delivery set 1
- 176 delivery set 2
- 177 delivery set 3
- 177 delivery set 4
- 177 delivery set 5

ophthalmology

- 178 ophthalmic set 2-IF
- 178 ophthalmic set 3-IF

neurosurgery and otolaryngology

- 179 otolaryngology set 1
- 179 otolaryngology set 2
- 179 craniotomy set 1-IF

cardiosurgery and angiography

- 180 ablation set 1-IF
- 180 angiography set 2

SURGICAL GOWNS

- 182 sterile gown NORMAL
- 182 surgical gown STANDARD **BESTSELLER!**
- 182 surgical gown STANDARD
- 182 surgical gown STANDARD
- 183 surgical gown STANDARD
- 183 surgical gown SOFT
- 183 surgical gown STANDART PLUS **BESTSELLER!**
- 183 surgical gown STANDART PLUS
- 184 surgical gown STANDART PLUS
- 184 surgical gown STANDART PLUS
- 184 surgical gown EXTRA SAFE
- 184 surgical gown COMFORT
- 185 surgical gown COMFORT PLUS

non-sterile surgical gowns

- 185 surgical gown STANDARD
- 185 surgical gown PREMIUM

SPORTS LINE pp.188-193

yellowBAND

- 190 cohesive bandage

yellowTAPE

- 190 kinesiotape

yellowRIGID TAPE

- 191 sports tape, line glue coating

yellowSPORTS TAPE

- 191 sports tape

yellowWRAP

- 191 foam underwrap

yellowFOAM

- 192 foam tape

scissors

- 192 for sports tapes

yellowBOX

- 192 dispenser for kinesiotapes

Comprehensive range of medical equipment

Operating theater is the heart of every hospital, where hundreds or even thousands of surgical procedures take place, during which the patient's skin layers are opened and cut. We present a comprehensive offer that allows you to protect the patient in the operating room while ensuring the safety of medical personnel.

Examination gloves

easyCARE **mediCARE**

Surgical gowns

ALPHAtex

Sets of surgical drapes and accesories **ALPHA**tex

adjusted to protect any medical procedure

Dressing materials

- swabs
- gauze lap sponges
- adhesive tapes
- island dressings
- special purpose dressings
- foil dressings

Products for sport enthuziasts and physiotherapists

yellow
SPORT

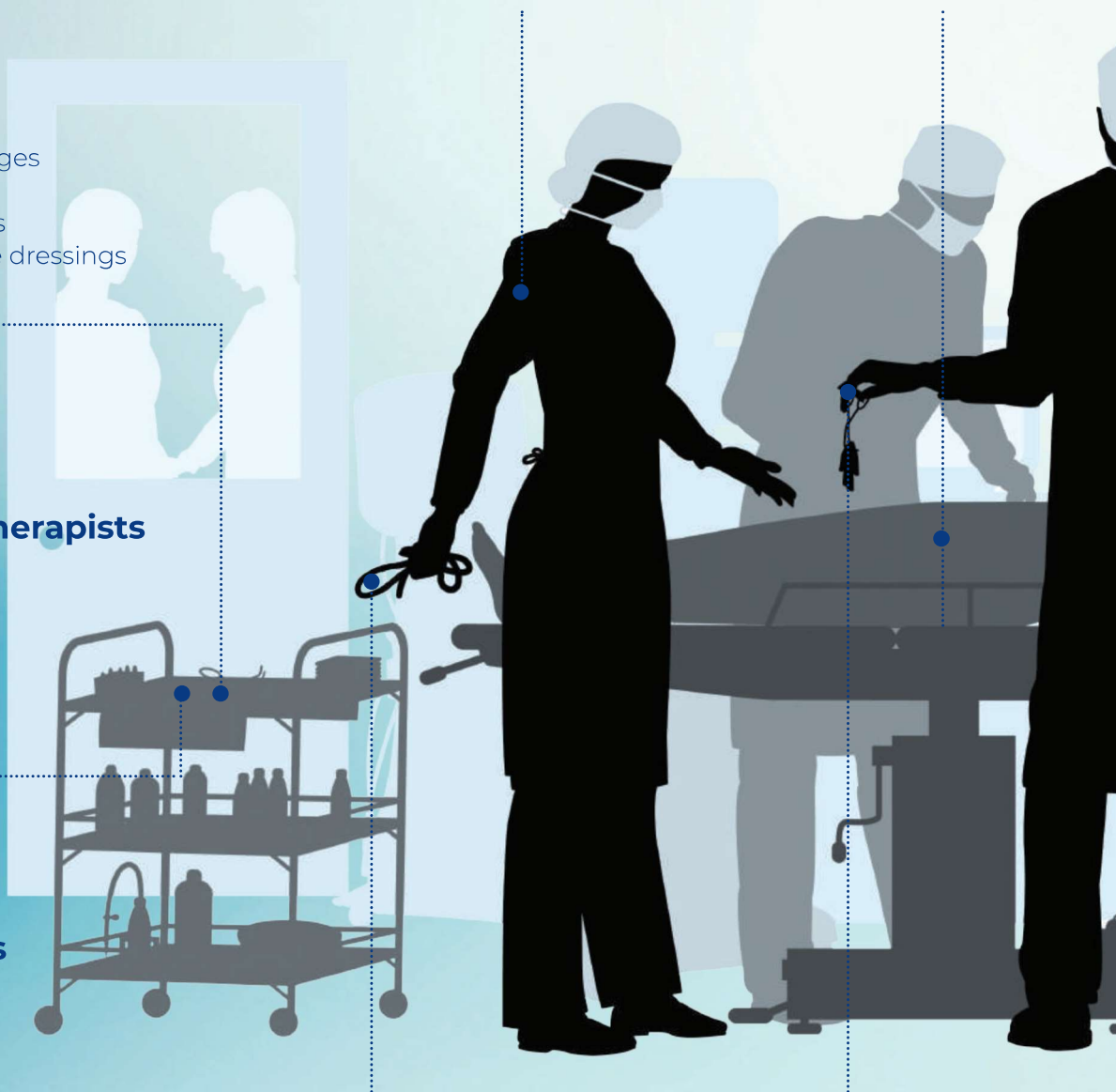
Surgical sutures

Suction sets

Pharmacy line
vitahealth

Specialistic disposable medical devices

Surgical gloves



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

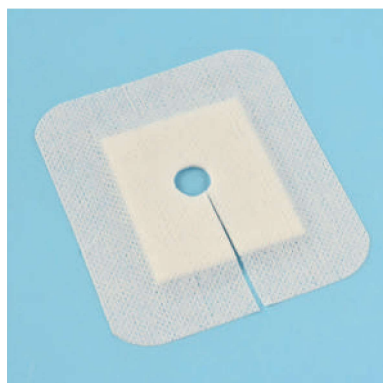
- designed to deliver oxygen with precise regulation of concentration, for high oxygen concentration

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.





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.

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**

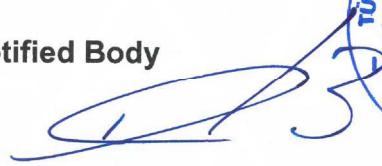
Registration No.: DD 60139535 0001
Report No.: 26300232 017

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

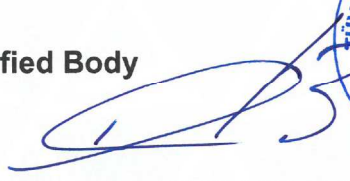
Products included:

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

Activity: Production

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

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