

DISPOSABLE MEDICAL BEDDING SET

non-sterile

features:

- made of polypropylene non-woven
- components:
 - bed sheet: 150 cm x 210 cm
 - quilt cover: 160 cm x 210 cm
 - pillow case: 70 cm x 80 cm



REF	grammage	colour	packaging unit
BT-ZES-25G3	25 g/m ²	green	1 set
BT-ZES-40G3	40 g/m ²	green	1 set
BT-ZES-40W3	40 g/m ²	white	1 set



bulk packaging:
25 x 1 set



available colours:



DISPOSABLE ABSORBENT UNDERPAD

non-sterile

features:

- composed of five layers:
 - lamine + cellulose wadding + cellulose pulp + cellulose wadding + PP nonwoven
- absorbent insert made of cellulose pulp
- impermeable foiled bottom



REF	dimensions	packaging unit
BT-PC4060	40 cm x 60 cm	25 pcs
BT-PC6060	60 cm x 60 cm	25 pcs
BT-PC6090	60 cm x 90 cm	25 pcs



bulk packaging:
4 x 25 pcs

DISPOSABLE ABSORBENT UNDERPAD

for operating table, non-sterile

features:

- quilted absorbent layer with addition of SAP (superabsorbent)
- composed of layers: polypropylene nonwoven, cellulose wadding, cellulose pulp with superabsorbent SAP, cellulose wadding, PE foil
- colour: absorbent layer - white, laminate - blue
- dimensions: 100 cm x 225 cm (absorbent layer 50 cm x 208 cm)



REF	dimensions	packaging unit
BT-PC100225	100 cm x 225 cm	10 pcs



bulk packaging:
2 x 10 pcs

easyFLOW TS

transfusion set, sterile

features

- 2-way sharp closure-piercing device of the drip chamber with anti-slip surface that guarantees tight and reliable connection with containers/bags
- air inlet with anti-bacterial filter and a coloured (red) flap
- pliable drip chamber
- dropper: 20 drops = 1 ml +/- 0,1 ml
- special blood filter with large area, pore size 200 µm
- min. 150 cm-long, soft, flexible tubing
- universal luer lock fitting at the end of tubing
- precise safe flow regulator with integrated holder for the closure-piercing device and with hook for securing the tubing
- name of the manufacturer placed on the flow regulator
- both tips of the device additionally secured with protective caps
- device available in a version containing phthalates and without phthalates
- single-use
- non-pyrogenic, non-toxic
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil with a coloured code (red) identifying the device

indication

- device used for the administration of blood and blood products

REF	version
TS	with phthalates
TS-BF	without phthalates

 **bulk packaging:**
250 pcs



3-way stopcock

sterile

features

- made of polycarbonate
- transparent housing
- clear optical identifier of open/close position (marked flow directions) operating in 360 degrees
- consistent, straight flow channels and an optimal internal diameter ensure correct pressure measurement
- rotating male luer lock
- all inlets protected with caps
- resistant to lipids
- latex-free, phthalate-free
- single-use
- non-pyrogenic, non-toxic
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device designed for managing the flow of infusion fluids during administration
- enables switching the infusion flow path
- for blood pressure monitoring
- for direct medicine/fluid supply

REF	colour	intermediate packaging
KT-002	blue	50 pcs

 **bulk packaging:**
20 x 50 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)
- 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



easyFLOW IS

infusion set, sterile

features

- 2-way sharp closure-piercing device of the drip chamber with anti-slip surface that guarantees tight and reliable connection with fluid containers/bags
- air inlet with anti-bacterial filter and coloured (blue) flap
- pliable drip chamber, size 6 cm, equipped with additional pressure wings to facilitate insertion into containers with liquids
- dropper: 20 drops = 1 ml +/- 0,1 ml
- fluid filter protecting against larger particles with pore size 15 µm
- min. 150 cm-long, soft, flexible tubing with luer lock conical fitting
- precise safe flow regulator with integrated holder for the closure-piercing device and with hook for securing the tubing
- name of the manufacturer placed on the flow regulator
- both tips of the device additionally secured with protective caps
- device available in a version containing phthalates and without phthalates
- single-use
- non-pyrogenic, non-toxic
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil with a coloured code (blue) identifying the device

indication

- device for fluid transfer in infusion therapy

REF	version		
IS	with phthalates	<div>  bulk packaging: 250 pcs </div>	<div>  BESTSELLER </div>
IS-BF	without phthalates		



extension tube for infusion pump


sterile

features

- tubing made of PVC
- device available in a transparent and amber version for photosensitive medicines
- diameter of the tubing - outer: 2,4 mm; inner: 1,24 mm
- luer lock fitting - male and female
- single-use
- latex-free, phthalate-free
- non-pyrogenic, non-toxic
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device used to extend infusion line

REF	colour of tube	length	intermediate packaging	
P450-BF	transparent	45 cm	50 pcs	<div>  bulk packaging: 24 x 50 pcs </div>
P1500-BF	transparent	150 cm	50 pcs	
PB1500-BF	amber	150 cm	50 pcs	



oropharyngeal airway/guedel airway

sterile

features

- made of high quality PE (polyethylene), free of PVC
- distinctive anatomical curve of airway tube allows for the opening of the upper respiratory tract and the free flow of anaesthetic gases, air
- colour coded sizes
- numeric marking of the size on the airway
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

indication

- used during artificial ventilation procedures to ensure the airway patency
- as a tool for paramedic to assist in the management of a casualty's airway which increases the effectiveness of the rescue operation
- facilitates the stabilization of the endotracheal tube and protects it against biting

REF	size	number	colour
RG-40	40 mm	000	pink
RG-50	50 mm	00	dark blue
RG-60	60 mm	0	black
RG-70	70 mm	1	white
RG-80	80 mm	2	green
RG-90	90 mm	3	yellow
RG-100	100 mm	4	red
RG-110	110 mm	5	blue
RG-120	120 mm	6	orange



bulk packaging:
100 x 1 pc.



air cushion anaesthetic mask

non-sterile

features

- due to the high quality of materials used, ventilation is conducted in an atraumatic and safe way for the patient
- anatomically shaped inflatable cuff, ensures perfect tightness of the mask with minimal pressure
- device, when applied to the face, tightly covers the patient's mouth and nose without compressing the eyes
- clear shell provides continuous visual observation of the patient
- colour-coded retaining rings, easy for size recognition
- retaining ring can be removed when it is not needed
- full size range allows to properly choose the size of the mask depending on the age of the patient
- all sizes are equipped with inflatable check valve to adjust air amount for best cushion fitting auto patient's face
- single-use
- latex-free, phthalate-free
- non-sterile
- packaging: 1 pc./foil

indication

- intended for the administration of a gas mixture coming through devices for artificial ventilation
- enables performing medical procedures including artificial ventilation, administration of anesthetic gas and carrying out emergency treatment of an unconscious patient

REF	size	age of patient/ size	colour
MAP-0	0	neonate	-
MAP-1	1	infant	-
MAP-2	2	pediatric	yellow
MAP-3	3	adult S	green
MAP-4	4	adult M	red
MAP-5	5	adult L	blue



bulk packaging:
100 x 1 pc.



dual-limb breathing circuit

sterile

features

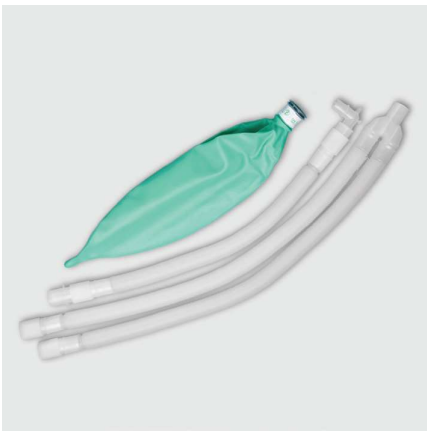
- made of high quality EVA material, without PVC
- 15F/22M and 22F universal connector fits compatible products and devices for mechanical ventilation or anesthesia machine
- expandable arms with maximum length of 160 cm
- adjustable length of circuit enabling adjustment of length of respiratory system 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.



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.



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.



nebulizer 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
- 8 ml nebulizer (graduated every 1 ml)
- average size of the molecule at a flow of 6l / min - 3,23 µm
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

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

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



bulk packaging:
50 x 1 pc.



multi-vent 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
- equipped with 2 jets - white to set mid flow concentration (35%, 40% and 50%) and green to set low concentration (24%, 28% and 30%)
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./foil

indication

- designed to deliver oxygen with precise regulation of concentration, regardless of way of patient's breathing


REF	length of tubing	size
MTDV-L	210 cm +/- 5%	L
MTDV-XL	210 cm +/- 5%	XL



bulk packaging:
100 x 1 pc.




STERILE SURGICAL DRAPE WITH ADHESIVE EDGE - 2-LAYERED

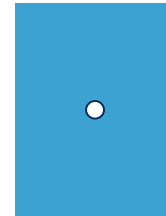
ref.	dimensions	packaging unit	 bulk packaging
AT-NFA-S 1	45cm x 45cm	1 pc.	230 pcs
AT-NFA-S 2	50cm x 50cm	1 pc.	200 pcs
AT-NFA-S 3	50cm x 60cm	1 pc.	280 pcs
AT-NFA-S 4	50cm x 70cm	1 pc.	210 pcs
AT-NFA-S 5	75cm x 75cm	1 pc.	135 pcs
AT-NFA-S 9	75cm x 90cm	1 pc.	125 pcs
AT-NFA-S 10	90cm x 120cm	1 pc.	80 pcs
AT-NFA-S 13	100cm x 150cm	1 pc.	50 pcs
AT-NFA-S 15	150cm x 180cm	1 pc.	20 pcs
AT-NFA-S 16	150cm x 210cm	1 pc.	20 pcs
AT-NFA-S 20	150cm x 240cm	1 pc.	20 pcs
AT-NFA-S 22	170cm x 300cm	1 pc.	20 pcs




adhesive tape
on the longer
side of drape


STERILE SURGICAL DRAPE WITH CENTRAL FENESTRATION - 2-LAYERED

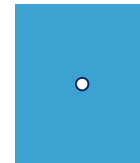
ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFF-S 2 E	45cm x 75cm	6cm x 8cm	100 pcs	4 x 100 pcs
AT-NFF-S 3 E	45cm x 60cm	ø 6cm	100 pcs	4 x 100 pcs
AT-NFF-S 4 E	75cm x 90cm	ø 7cm	50 pcs	4 x 50 pcs
AT-NFF-S 5 E	75cm x 90cm	6cm x 8cm	50 pcs	4 x 50 pcs




economic
version

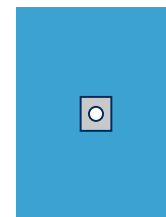
STERILE SURGICAL DRAPE WITH CENTRAL FENESTRATION - 2-LAYERED

ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFF-S 1	45cm x 45cm	ø 6cm	1 pc.	200 pcs
AT-NFF-S 21	50cm x 60cm	ø 7cm	1 pc.	300 pcs
AT-NFF-S 2	50cm x 75cm	6cm x 8cm	1 pc.	120 pcs
AT-NFF-S 3	50cm x 75cm	ø 7cm	1 pc.	120 pcs
AT-NFF-S 4	75cm x 90cm	ø 7cm	1 pc.	120 pcs
AT-NFF-S 5	75cm x 90cm	6cm x 8cm	1 pc.	120 pcs
AT-NFF-S 6	90cm x 120cm	ø 10cm	1 pc.	120 pcs




STERILE SURGICAL DRAPE WITH CENTRAL ADHESIVE FENESTRATION - 2-LAYERED

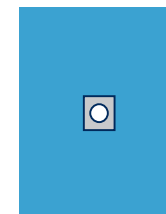
ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFFA-S 1 E	45cm x 45cm	ø 5cm	100 pcs	4 x 100 pcs
AT-NFFA-S 2 E	45cm x 75cm	6cm x 8cm	100 pcs	4 x 100 pcs
AT-NFFA-S 3 E	50cm x 60cm	ø 6cm	100 pcs	4 x 100 pcs
AT-NFFA-S 4 E	75cm x 90cm	ø 7cm	50 pcs	4 x 50 pcs
AT-NFFA-S 5 E	75cm x 90cm	6cm x 8cm	50 pcs	4 x 50 pcs
AT-NFFA-S 6 E	90cm x 120cm	ø 8cm	50 pcs	4 x 50 pcs




economic
version

STERILE SURGICAL DRAPE WITH CENTRAL ADHESIVE FENESTRATION - 2-LAYERED

ref.	dimensions	fenestration	packaging unit	 bulk packaging
AT-NFFA-S 1	45cm x 45cm	ø 6cm	1 pc.	200 pcs
AT-NFFA-S 11	50cm x 60cm	6cm x 8cm	1 pc.	200 pcs
AT-NFFA-S 3	50cm x 75cm	ø 7cm	1 pc.	120 pcs
AT-NFFA-S 4	75cm x 90cm	ø 7cm	1 pc.	100 pcs
AT-NFFA-S 5	75cm x 90cm	6cm x 8cm	1 pc.	100 pcs
AT-NFFA-S 6	90cm x 120cm	ø 10cm	1 pc.	60 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

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



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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

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