

# dispoFINE

## injection needle, sterile

### features

- needle tube is made of smooth and durable stainless steel
- sheath and hub made of polypropylene
- thin walls assure adequate stream pace
- tip sharpened in three surfaces (back cut)
- bevel type: LB/BL standard long bevel
- surface of needle tube covered with sliding agent (silicone)
- glued needle elements to prevent their separation (glue - epoxy resin)
- hubs coloured in accordance with ISO code allowing fast recognition of needle size
- latex-free, phthalate-free
- non-toxic, non-pyrogenic
- EO sterilized
- packaging: 1 pc./paper-foil

### indication

- device designed for intravenous, intramuscular and hypodermic injections



| REF       | size            | colour      | G  | intermediate packaging |
|-----------|-----------------|-------------|----|------------------------|
| IN-03X13  | 0,3 mm x 13 mm  | yellow      | 30 | 100 pcs                |
| IN-04X19  | 0,4 mm x 19 mm  | medium grey | 27 | 100 pcs                |
| IN-045X12 | 0,45 mm x 12 mm | brown       | 26 | 100 pcs                |
| IN-045X16 | 0,45 mm x 16 mm | brown       | 26 | 100 pcs                |
| IN-045X22 | 0,45 mm x 22 mm | brown       | 26 | 100 pcs                |
| IN-05X16  | 0,5 mm x 16 mm  | orange      | 25 | 100 pcs                |
| *IN-05X20 | 0,5 mm x 20 mm  | orange      | 25 | 100 pcs                |
| IN-05X25  | 0,5 mm x 25 mm  | orange      | 25 | 100 pcs                |
| IN-05X40  | 0,5 mm x 40 mm  | orange      | 25 | 100 pcs                |
| IN-06X25  | 0,6 mm x 25 mm  | deep blue   | 23 | 100 pcs                |
| IN-06X30  | 0,6 mm x 30 mm  | deep blue   | 23 | 100 pcs                |
| IN-06X40  | 0,6 mm x 40 mm  | deep blue   | 23 | 100 pcs                |
| IN-07X30  | 0,7 mm x 30 mm  | black       | 22 | 100 pcs                |
| IN-07X40  | 0,7 mm x 40 mm  | black       | 22 | 100 pcs                |
| *IN-07X50 | 0,7 mm x 50 mm  | black       | 22 | 100 pcs                |

| REF       | size           | colour     | G  | intermediate packaging |
|-----------|----------------|------------|----|------------------------|
| IN-08X25  | 0,8 mm x 25 mm | deep green | 21 | 100 pcs                |
| IN-08X40  | 0,8 mm x 40 mm | deep green | 21 | 100 pcs                |
| *IN-08X50 | 0,8 mm x 50 mm | deep green | 21 | 100 pcs                |
| IN-09X25  | 0,9 mm x 25 mm | yellow     | 20 | 100 pcs                |
| IN-09X40  | 0,9 mm x 40 mm | yellow     | 20 | 100 pcs                |
| IN-11X40  | 1,1 mm x 40 mm | cream      | 19 | 100 pcs                |
| IN-12X40  | 1,2 mm x 40 mm | pink       | 18 | 100 pcs                |
| IN-12X50  | 1,2 mm x 50 mm | pink       | 18 | 100 pcs                |
| IN-16X40  | 1,6 mm x 40 mm | white      | 16 | 100 pcs                |
| IN-18X40  | 1,8 mm x 40 mm | blue-grey  | 15 | 100 pcs                |
| IN-21X40  | 2,1 mm x 40 mm | pale green | 14 | 100 pcs                |

 bulk packaging:  
50 x 100 pcs

 available  
on request

# dispoGUARD

## safety injection needle, sterile

### features

- safety cover can be activated with one hand and it shields needle immediately after injection
- cover integrated with needle
- tip sharpened in three surfaces (back cut)
- colour coding system for size, marked on hub
- activation of safety mechanism signalized by audible click
- needle is securely closed inside activated safety cover
- latex-free, phthalate-free
- non-toxic, non-pyrogenic
- EO sterilized
- packaging: 1 pc./paper-foil

### indication

- device designed for intravenous, intramuscular and hypodermic injections



| REF        | size            | colour     | G  | intermediate packaging |
|------------|-----------------|------------|----|------------------------|
| INB-03X13  | 0,3 mm x 13 mm  | yellow     | 30 | 50 pcs                 |
| INB-045X12 | 0,45 mm x 12 mm | brown      | 26 | 50 pcs                 |
| INB-05X25  | 0,5 mm x 25 mm  | orange     | 25 | 50 pcs                 |
| INB-05X40  | 0,5 mm x 40 mm  | orange     | 25 | 50 pcs                 |
| INB-06X25  | 0,6 mm x 25 mm  | deep blue  | 23 | 50 pcs                 |
| INB-06X30  | 0,6 mm x 30 mm  | deep blue  | 23 | 50 pcs                 |
| INB-07X30  | 0,7 mm x 30 mm  | black      | 22 | 50 pcs                 |
| INB-07X40  | 0,7 mm x 40 mm  | black      | 22 | 50 pcs                 |
| INB-08X40  | 0,8 mm x 40 mm  | deep green | 21 | 50 pcs                 |
| INB-09X40  | 0,9 mm x 40 mm  | yellow     | 20 | 50 pcs                 |
| INB-11X40  | 1,1 mm x 40 mm  | cream      | 19 | 50 pcs                 |
| INB-12X40  | 1,2 mm x 40 mm  | pink       | 18 | 50 pcs                 |

 bulk packaging:  
50 x 50 pcs

# 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
- special design of the 1 ml syringe plunger stopper reduces dead space
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage, adequately:
  - every 0,01ml for capacity of 1ml
  - 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 50/60 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          | type | capacity | position of nozzle | intermediate packaging | bulk packaging |
|--------------|------|----------|--------------------|------------------------|----------------|
| 001ML-3CZ-BL | luer | 1 ml     | centric            | 100 pcs                | 32 x 100 pcs   |
| 002ML-3CZ-BL | luer | 2 ml     | centric            | 100 pcs                | 30 x 100 pcs   |
| 005ML-3CZ-BL | luer | 5 ml     | centric            | 100 pcs                | 24 x 100 pcs   |
| 010ML-3CZ-BL | luer | 10 ml    | centric            | 100 pcs                | 16 x 100 pcs   |
| 020ML-3CZ-BL | luer | 20 ml    | eccentric          | 50 pcs                 | 16 x 50 pcs    |
| 050ML-3CZ-BL | luer | 50/60 ml | eccentric          | 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 50/60 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             | type      | capacity | position of nozzle | colour of plunger | intermediate packaging | bulk packaging |
|-----------------|-----------|----------|--------------------|-------------------|------------------------|----------------|
| 003ML-3CZ-LL-BL | luer lock | 3 ml     | centric            | green             | 100 pcs                | 30 x 100 pcs   |
| 005ML-3CZ-LL-BL | luer lock | 5 ml     | centric            | green             | 100 pcs                | 24 x 100 pcs   |
| 010ML-3CZ-LL-BL | luer lock | 10 ml    | centric            | green             | 100 pcs                | 16 x 100 pcs   |
| 020ML-3CZ-LL-BL | luer lock | 20 ml    | centric            | green             | 50 pcs                 | 16 x 50 pcs    |
| 030ML-3CZ-LL-BL | luer lock | 30 ml    | centric            | green             | 50 pcs                 | 16 x 50 pcs    |
| 050ML-3CZ-LL-BL | luer lock | 50/60 ml | centric            | green             | 25 pcs                 | 16 x 25 pcs    |

### amber type

|                   |           |          |         |       |        |             |
|-------------------|-----------|----------|---------|-------|--------|-------------|
| 050ML-3CZ-LL-B-BL | luer lock | 50/60 ml | centric | white | 25 pcs | 16 x 25 pcs |
|-------------------|-----------|----------|---------|-------|--------|-------------|



## feeding tube graduated, with X-ray contrast

### sterile

#### features

- made of soft PVC with a frosted surface, resistant to bending and kinking due to the appropriate degree of hardness
- atraumatic, soft rounded, closed tip facilitates precise insertion of catheter
- two alternate end holes with gently stretched edges
- connector compatible with the conical tip of luer syringe
- integrated stopper allows the tube to be closed tightly
- colour-coded connectors for size recognition, numerical size identification on packaging
- radiopaque line along the entire length of the catheter
- digital depth graduation every 1 cm (from 5 cm to 40 cm)
- length 50 cm
- name of the manufacturer placed on the catheter
- individually packed straight
- latex-free
- phthalate-free
- single-use
- EO sterilized
- shelf life: 5 years
- packaging: 1 pc. / paper-foil

#### indication

- device inserted through patient's nose or mouth to perform enteral nutrition

| REF       | size  | length | colour     | intermediate packaging |
|-----------|-------|--------|------------|------------------------|
| CKS-04-50 | CH 4  | 500 mm | red        | 100 pcs                |
| CKS-05-50 | CH 5  | 500 mm | grey       | 100 pcs                |
| CKS-06-50 | CH 6  | 500 mm | pink       | 100 pcs                |
| CKS-08-50 | CH 8  | 500 mm | pale green | 100 pcs                |
| CKS-10-50 | CH 10 | 500 mm | black      | 100 pcs                |



bulk packaging:  
10 x 100 pcs



## suction catheter

### sterile

#### features

- made of soft and flexible PVC, that is resistant to bending and kinking
- frozen surface prevents the catheter from sticking to the wall of the endotracheal tube
- atraumatic, soft rounded, open tip
- tip with two alternating lateral eyes with smooth edges
- colour-coded connectors for size recognition, numerical size identification on the packaging
- latex-free
- single-use
- EO sterilized
- packaging: 1 pc./paper-foil

#### indication

- device designed for suction of secretions from the upper respiratory tract
- recommended for source of suction with its own suction force regulation

| REF       | size  | length | colour      | intermediate packaging |
|-----------|-------|--------|-------------|------------------------|
| CO-B06-40 | CH 6  | 400 mm | light green | 50 pcs                 |
| CO-B08-40 | CH 8  | 400 mm | blue        | 50 pcs                 |
| CO-B10-40 | CH 10 | 400 mm | black       | 50 pcs                 |
| CO-B12-50 | CH 12 | 500 mm | white       | 50 pcs                 |
| CO-B12-60 | CH 12 | 600 mm | white       | 50 pcs                 |
| CO-B14-50 | CH 14 | 500 mm | green       | 50 pcs                 |
| CO-B14-60 | CH 14 | 600 mm | green       | 50 pcs                 |
| CO-B16-50 | CH 16 | 500 mm | orange      | 50 pcs                 |
| CO-B16-60 | CH 16 | 600 mm | orange      | 50 pcs                 |
| CO-B18-50 | CH 18 | 500 mm | red         | 50 pcs                 |
| CO-B18-60 | CH 18 | 600 mm | red         | 50 pcs                 |
| CO-B20-50 | CH 20 | 500 mm | yellow      | 50 pcs                 |
| CO-B20-60 | CH 20 | 600 mm | yellow      | 50 pcs                 |
| CO-B22-50 | CH 22 | 500 mm | purple      | 50 pcs                 |
| CO-B22-60 | CH 22 | 600 mm | purple      | 50 pcs                 |



bulk packaging:  
10 x 50 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



## 3-way stopcock with extension tube

### sterile

#### features

- three-way stopcock with an extension tube of various lengths (from 7 cm to 100 cm)
- transparent housing
- clear optical identifier of open/close position (marked flow directions)
- three-way stopcock made of polycarbonate, extension tube made of PVC
- 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     | length of tube | intermediate packaging |
|---------|----------------|------------------------|
| KTP-7   | 7 cm           | 50 pcs                 |
| KTP-10  | 10 cm          | 50 pcs                 |
| KTP-25  | 25 cm          | 50 pcs                 |
| KTP-50  | 50 cm          | 50 pcs                 |
| KTP-75  | 75 cm          | 50 pcs                 |
| KTP-100 | 100 cm         | 50 pcs                 |



bulk packaging:  
20 x 50 pcs



# needle-free valve

sterile

## features

- body made of transparent material - polycarbonate
- high-quality silicone membrane allows multiple port injections
- flat injection surface - smooth and evenly ended port membrane that facilitates disinfection
- metal-free, suitable for MRI examination
- male connector of the transparent port is secured with a cap allowing for aseptic removal of the item from the packaging
- may be used for 7 days or up to 350 activations
- priming capacity: 0,09 ml
- high flow rate: 350 ml/min
- withstands injection fluid pressure of 3 bars (44 PSI)
- withstands back pressure of 2 bars (29 PSI)
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- intended for closing infusion ports
- device intended for multiple, needle-free injections (liquid drug administration, blood sample taking)
- protects infusion lines from contamination and infection during infusion therapy
- does not require using safety caps
- dedicated for standard luer and luer lock connectors

| REF  | colour      | intermediate packaging |
|------|-------------|------------------------|
| PB-N | blue        | 100 pcs                |
| PB-T | transparent | 100 pcs                |

 bulk packaging:  
20 x 100 pcs



# cannula stopper

sterile

## features

- precisely and safely closes standard ports
- luer lock stopper has only one male tip
- combi stopper with male and female tip especially dedicated for securing luer lock fitting in infusion and transfusion sets
- single-use
- non-pyrogenic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- as a stopper of intravenous cannulas, ports and catheters
- intended to be used in combination with other devices during infusion therapy, protecting against the outflow of blood through the cannula and protecting against contamination and infection

| REF   | type      | intermediate packaging | bulk packaging |
|-------|-----------|------------------------|----------------|
| KDKLL | luer lock | 250 pcs                | 10 x 250 pcs   |
| KDKC  | combi     | 100 pcs                | 50 x 100 pcs   |



# samples taking urine bag

## sterile

### features

- latex-free bag with a capacity of 100 ml, size 19 cm x 7 cm
- made of delicate, durable PE foil
- easy-to-read scale, adequate for diuresis measurement, highly accurate - every 10 ml
- adhesive part of the bag coated with anti-allergic, high-quality glue
- additional sealing made of anti-allergic foam that protects against the wall sticking of the bag, thanks to which free flow of urine is possible
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

### indication

- for urine sample collection in infants and small children



| REF      | capacity | purpose   | version        | intermediate packaging |
|----------|----------|-----------|----------------|------------------------|
| WMCH-001 | 100 ml   | for boys  | with sponge    | 100 pcs                |
| WMCH-002 | 100 ml   | for boys  | without sponge | 100 pcs                |
| WMDZ-001 | 100 ml   | for girls | with sponge    | 100 pcs                |
| WMDZ-002 | 100 ml   | for girls | without sponge | 100 pcs                |



bulk packaging:  
25 x 100 pcs

# urine bag hanger

## non-sterile

### features

- made of strong and durable plastic
- special clamp that prevents tube bending
- suitable for round and square bed rails
- two handles on each side for hanging urine bags of various sizes
- manufacturer's name placed on the device
- latex-free, phthalate-free
- non-sterile

### indication

- for hanging standard urine collection bags



| REF   | intermediate packaging |
|-------|------------------------|
| WNM01 | 50 pcs                 |



bulk packaging:  
4 x 50 pcs

# enema bag

## sterile

### features

- bag with a capacity of 1750 ml with two holes for hanging
- made of medical PVC
- scaled from 50 ml to 1750 ml
- linear scale every 100 ml, digital scale every 200 ml
- tube with a length of 150 cm with a sliding clamp, ended with an atraumatic opening and one lateral opening
- tube end is secured with a tube cap
- upper part of the bag is reinforced with an additional flange stabilizing the inlet during filling with liquid
- flange is equipped with a non-return valve
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./foil

### indication

- bag that allows introduction of fluid into the large bowel through the anus to remove fecal material and stimulate peristaltic bowel movement



| REF |
|-----|
| WLS |



bulk packaging:  
150 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.



## 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.      |





# laryngeal mask

PVC, sterile

## features

- made of medical PVC
- elastic mask body with description (size, cuff volume, suggested patient's weight)
- elliptic shape, flexible sealing cuff and universal, transparent connector: 15 mm
- colour-coded valve protection makes it easy to quickly recognize size
- single-use
- latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- device inserted through the mouth, up to the back of the throat, forms a seal at the top of the glottis in order to:
  - direct protecting the patient's airway patency
  - artificial ventilation also during cardiopulmonary resuscitation
  - maintaining airway patency in: short-term surgical procedures, without the need of muscles relaxation, when endotracheal intubation is not necessary and under anesthesia for diagnostic procedures



| REF     | size | colour of valve protection | weight of patient | max. inflation | intermediate packaging |
|---------|------|----------------------------|-------------------|----------------|------------------------|
| MKPJ-10 | 1    | pink                       | ≤ 5 kg            | 4 ml           | 5 pcs                  |
| MKPJ-15 | 1.5  | orange                     | 5-10 kg           | 7 ml           | 5 pcs                  |
| MKPJ-20 | 2    | dark green                 | 10-20 kg          | 10 ml          | 5 pcs                  |
| MKPJ-25 | 2.5  | brown                      | 20-30 kg          | 14 ml          | 5 pcs                  |
| MKPJ-30 | 3    | green                      | 30-50 kg          | 20 ml          | 5 pcs                  |
| MKPJ-40 | 4    | purple                     | 50-70 kg          | 30 ml          | 5 pcs                  |
| MKPJ-50 | 5    | dark blue                  | 70-100 kg         | 40 ml          | 5 pcs                  |



bulk packaging:  
10 x 5 pcs

# laryngeal mask

silicone, sterile

## features

- made of biocompatible silicone, which ensures excellent flexibility of the device
- elastic mask body with description (size, cuff volume, suggested patient's weight)
- elliptic shape, flexible sealing cuff and universal, transparent connector: 15 mm
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

## indication

- device inserted through the mouth, up to the back of the throat, forms a seal at the top of the glottis in order to:
  - direct protecting the patient's airway patency
  - artificial ventilation also during cardiopulmonary resuscitation
  - maintaining airway patency in: short-term surgical procedures, without the need of muscles relaxation, when endotracheal intubation is not necessary and under anesthesia for diagnostic procedures



| REF     | size | weight of patient | max. inflation | intermediate packaging |
|---------|------|-------------------|----------------|------------------------|
| MKSJ-10 | 1    | ≤ 5 kg            | 4 ml           | 5 pcs                  |
| MKSJ-15 | 1.5  | 5-10 kg           | 7 ml           | 5 pcs                  |
| MKSJ-20 | 2    | 10-20 kg          | 10 ml          | 5 pcs                  |
| MKSJ-25 | 2.5  | 20-30 kg          | 14 ml          | 5 pcs                  |
| MKSJ-30 | 3    | 30-50 kg          | 20 ml          | 5 pcs                  |
| MKSJ-40 | 4    | 50-70 kg          | 30 ml          | 5 pcs                  |
| MKSJ-50 | 5    | 70-100 kg         | 40 ml          | 5 pcs                  |



bulk packaging:  
10 x 5 pcs

## intubation stylet

sterile

### features

- made of PVC-coated aluminium
- special material for both stiffness and pliability
- intended for use during difficult intubation
- size and diameter markings
- soft distal tip
- single-use
- phthalate-free
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

### indication

- allows you to give the endotracheal tube the right curvature
- introduced to the endotracheal tube facilitates intubation in routine and difficult cases, when the laryngeal inlet is not visible



| REF    | size  | diameter | length       | tube size        | intermediate packaging | bulk packaging |
|--------|-------|----------|--------------|------------------|------------------------|----------------|
| PRI-06 | 6 Fr  | 2,0 mm   | 310 mm (±10) | from 2,0 to 4,0  | 20 pcs                 | 20 x 20 pcs    |
| PRI-10 | 10 Fr | 3,3 mm   | 390 mm (±10) | from 4,5 to 6,5  | 20 pcs                 | 20 x 20 pcs    |
| PRI-14 | 14 Fr | 4,7 mm   | 390 mm (±10) | from 7,0 to 10,0 | 20 pcs                 | 20 x 20 pcs    |

## tracheal tube introducer

curved, sterile

### features

- made of medical grade low density polyethylene
- curved and rounded tip enables safe intubation without damaging the soft tissues
- optimum flexibility and rigidity facilitate correct insertion and safe removal of the introducer after intubation
- imprint of the size, diameter and manufacturer's name on the device
- bright yellow body for increased visibility of the introducer in the tracheal tube canal
- clear, easy to read graduation every 1 cm
- available in three sizes and lengths
- single-use
- PVC free
- latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

### indication

- for use during difficult intubation procedures
- as an aid to facilitate the insertion of the endotracheal tube during standard intubation



bulk packaging:  
20 x 10 pcs

| REF         | size  | diameter O.D. | total length | tube size        | graduation | intermediate packaging |
|-------------|-------|---------------|--------------|------------------|------------|------------------------|
| PTIZ-06-535 | 6 Fr  | 2,0 mm        | 535 mm       | from 2,0 to 4,0  | 10 – 45 mm | 10 pcs                 |
| PTIZ-10-600 | 10 Fr | 3,3 mm        | 600 mm       | from 4,5 to 6,0  | 10 – 50 mm | 10 pcs                 |
| PTIZ-10-800 | 10 Fr | 3,3 mm        | 800 mm       | from 4,5 to 6,0  | 10 – 60 mm | 10 pcs                 |
| PTIZ-15-600 | 15 Fr | 5,0 mm        | 600 mm       | from 6,5 to 10,0 | 10 – 50 mm | 10 pcs                 |
| PTIZ-15-800 | 15 Fr | 5,0 mm        | 800 mm       | from 6,5 to 10,0 | 10 – 60 mm | 10 pcs                 |



## endotracheal tube

uncuffed, sterile

### features

- made of flexible PVC
- radiopaque line over the entire tube length
- equipped with lateral Murphy eye
- graduated every 1 cm
- double depth marker to control the position of the tube
- tube size marked in 3 places (on the connector 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

| REF     | size           | intermediate packaging |
|---------|----------------|------------------------|
| RIB-20  | I.D. (mm) 2.0  | 20 pcs                 |
| RIB-25  | I.D. (mm) 2.5  | 20 pcs                 |
| RIB-30  | I.D. (mm) 3.0  | 20 pcs                 |
| RIB-35  | I.D. (mm) 3.5  | 20 pcs                 |
| RIB-40  | I.D. (mm) 4.0  | 20 pcs                 |
| RIB-45  | I.D. (mm) 4.5  | 20 pcs                 |
| RIB-50  | I.D. (mm) 5.0  | 20 pcs                 |
| RIB-55  | I.D. (mm) 5.5  | 20 pcs                 |
| RIB-60  | I.D. (mm) 6.0  | 20 pcs                 |
| RIB-65  | I.D. (mm) 6.5  | 20 pcs                 |
| RIB-70  | I.D. (mm) 7.0  | 20 pcs                 |
| RIB-75  | I.D. (mm) 7.5  | 20 pcs                 |
| RIB-80  | I.D. (mm) 8.0  | 20 pcs                 |
| RIB-85  | I.D. (mm) 8.5  | 20 pcs                 |
| RIB-90  | I.D. (mm) 9.0  | 20 pcs                 |
| RIB-95  | I.D. (mm) 9.5  | 20 pcs                 |
| RIB-100 | I.D. (mm) 10.0 | 20 pcs                 |



bulk packaging:  
10 x 20 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



# 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    | intermediate packaging |
|--------|--------|--------|-----------|------------------------|
| RG-40  | 40 mm  | 000    | pink      | 50 pcs                 |
| RG-50  | 50 mm  | 00     | dark blue | 50 pcs                 |
| RG-60  | 60 mm  | 0      | black     | 50 pcs                 |
| RG-70  | 70 mm  | 1      | white     | 50 pcs                 |
| RG-80  | 80 mm  | 2      | green     | 50 pcs                 |
| RG-90  | 90 mm  | 3      | yellow    | 50 pcs                 |
| RG-100 | 100 mm | 4      | red       | 50 pcs                 |
| RG-110 | 110 mm | 5      | blue      | 50 pcs                 |
| RG-120 | 120 mm | 6      | orange    | 50 pcs                 |



bulk packaging:  
10 x 50 pcs

# 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   |
| MAP-6 | 6    | adult XL            | orange |



bulk packaging:  
100 x 1 pc.

## ID wristband

non-sterile

### features

- durable wristband coating characterized by high humidity resistance and resistance to the activity of soaps, hand disinfectants and other liquids used in hospitals
- made of soft and delicate vinyl
- flexible, delicate, very light and easy to put on
- rounded edges prevent from injuring
- high tensile strength
- colour marking depending on the purpose
- single-use fastening resistant to accidental break
- hypoallergenic, latex-free, phthalate-free
- available in a version with a description field directly on the band and with an insert card
- non-sterile
- packaging: 100 pcs/box

### indication

- for identification of patients in hospital wards

| REF      | purpose                 | colour | version     | intermediate packaging |
|----------|-------------------------|--------|-------------|------------------------|
| OPD-B-01 | for children and adults | white  | insert card | 100 pcs                |
| OPN-R-01 | for infants             | pink   | insert card | 100 pcs                |
| OPN-N-01 | for infants             | blue   | insert card | 100 pcs                |



bulk packaging:  
50 x 100 pcs



## entrance mat

non-sterile

### features

- blue mat consisting of 30 layers - thin sticky sheets
- each of the sticky sheets made of polyethylene resin
- does not contain heavy metals
- excellent adhesive properties
- the first and last sheets secured with a non-adhesive foil
- low mat profile: app. 2 mm thick
- the bottom surface adheres very well to the floor over the entire surface, preventing adverse movement of the mat, allowing trouble-free passage of trolleys with equipment or beds, without the risk of curling up the mat or tearing
- no need to clean the mat - as soon as the surface of the mat is contaminated, it should be torn off to uncover a new, clean sheet
- there is numbering of sheets on a white non-adhesive material in the mat corner facilitate quick identification and easy removal of subsequent sheets
- light, easy to spread
- non-sterile

### indication

- preventing spreading of contamination brought on shoe soles and wheelchairs to operating rooms

| REF  | dimensions     | intermediate packaging |
|------|----------------|------------------------|
| M001 | 45 cm x 115 cm | 10 pcs                 |



bulk packaging:  
5 x 10 pcs



## 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

90



## non-woven dressing with absorbent pad

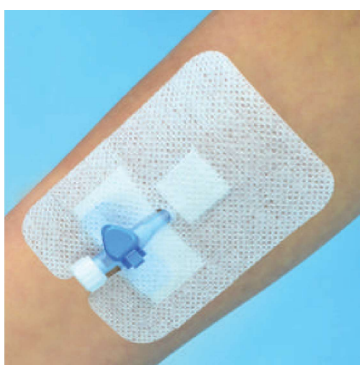
### elastopor STERIL



#### 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.         |



## non-woven IV cannula dressing

### elastopor IV



#### features

- centrally situated absorbent pad protects the non-woven material from sticking to the injection site
- non-woven lining should be placed under cannula's wings, which prevents it from causing damage to the skin

#### indication

- dressing application around the inserted cannula
- stabilization, protection and fixation of intravenous cannulas

| REF    | dimensions      | packaging unit paper-paper | bulk packaging box |
|--------|-----------------|----------------------------|--------------------|
| 811013 | 6 cm x 8 cm     | 1 pc.                      | 100 x 1 pc.        |
| 811012 | 5,1 cm x 7,6 cm | 1 pc.                      | 100 x 1 pc.        |
| 811023 | 6 cm x 8 cm     | 1 pc.                      | 50 x 1 pc.         |
| 811022 | 5,1 cm x 7,6 cm | 1 pc.                      | 50 x 1 pc.         |

## 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



130

| REF         | grammage            | colour | packaging unit |
|-------------|---------------------|--------|----------------|
| BT-ZES-25G3 | 25 g/m <sup>2</sup> | green  | 1 set          |
| BT-ZES-40G3 | 40 g/m <sup>2</sup> | green  | 1 set          |
| BT-ZES-40W3 | 40 g/m <sup>2</sup> | 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
- single use



| 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 five layers: polypropylene non-woven, cellulose wadding, cellulose pulp with superabsorbent SAP, cellulose wadding, PE foil
- impermeable foiled bottom
- single use



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



bulk packaging:  
2 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**

**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 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**

**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**

**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

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  
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**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