

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 signaled 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

safeLANCE

pressure-activated safety lancet, sterile

features

- easy to use, minimizes unpleasant feelings
- special construction allows lancet tip to be automatically inserted into finger pad and then to be retracted so that needle is not visible before or after puncturing
- correctly matched size of lancet allows you to get optimal amount of blood with minimal patient's pain
- design ensures safety for medical personnel and patient by eliminating accidental puncture and infection
- perfect guidance of lancet needle inside housing reduces vibration, thus decreases patient's pain and prevents damage to skin tissue
- available in two sizes:
 - 23 G, puncture depth 1,8 mm - green, dedicated for women and children
 - 21 G, puncture depth 2,4 mm - pink, dedicated for men
- latex-free, phthalate-free
- single-use
- sterilized by radiation
- packaging: 100 pcs/box

indication

- capillary blood sampling from fingertip or ear flap for testing, for example, glucose level

REF	size / puncture depth	colour	intermediate packaging
NA-18	23 G / 1,8 mm	green	100 pcs
NA-24	21 G / 2,4 mm	pink	100 pcs



bulk packaging:
20 x 100 pcs



dispoSULIN

insulin pen needle, sterile

features

- made of polypropylene, polyethylene and stainless steel
- triple-point needle blade allows easy and atraumatic skin penetration
- covering the needle with silicone lubricant reduces resistance during injection
- thin walls of needle ensure easy flow of medicine and the right flow rate
- coloured cap and paper cover of packaging make it easy to quickly recognize size of needle
- available in various sizes, allowing you to adapt to individual needs
- universal, compatible with all pen models
- single-use
- non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 100 pcs/box

indication

- for subcutaneous injection
- dedicated for use with pre-filled pens (insulin pens)

REF	size	colour	G	intermediate packaging
INP-033X12	0,33 mm x 12 mm	pink	29	100 pcs
INP-030X08	0,30 mm x 8 mm	yellow	30	100 pcs
INP-025X06	0,25 mm x 6 mm	purple	31	100 pcs
INP-025X08	0,25 mm x 8 mm	blue	31	100 pcs



bulk packaging:
50 x 100 pcs



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

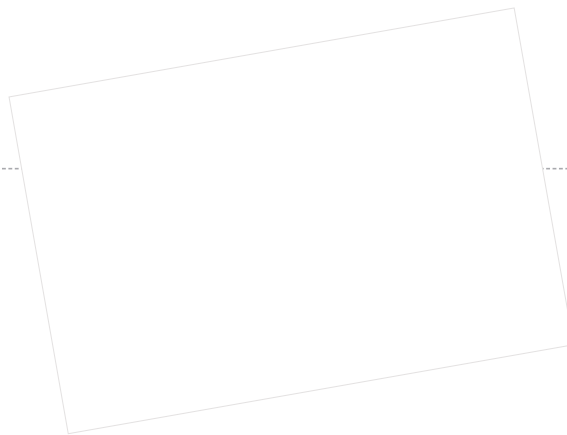
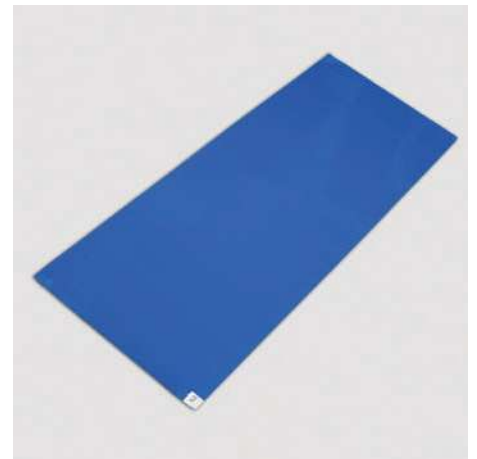
indication

- 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



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.



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



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%, 26%, 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.



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



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.

duoNEX

single-use syringe, 2-part, luer, sterile

features

- white line
- transparent barrel allows full visual control of content
- white contrasting plunger
- luer nozzle centrally located in 2 ml syringe, eccentric in 5, 10, 20 ml syringes
- smooth plunger sliding
- limitation flange securing against accidental removal of plunger
- 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
 - every 0,5 ml for capacity of 10 ml
 - every 1 ml for capacity of 20 ml
- extended graduation that includes a 10% extension of the nominal capacity
- name of syringe and manufacturer's logo placed on barrel
- single-use
- non-pyrogenic, non-toxic
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- 2-piece syringe for subcutaneous, intramuscular and intravenous infusions 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
002ML-2CZ-B	luer	2 ml	centric	100 pcs	30 x 100 pcs
005ML-2CZ-B	luer	5 ml	eccentric	100 pcs	24 x 100 pcs
010ML-2CZ-B	luer	10 ml	eccentric	100 pcs	16 x 100 pcs
020ML-2CZ-B	luer	20 ml	eccentric	50 pcs	16 x 50 pcs



dicoNEX SN

single-use syringe, 3-part, luer, with needle alongside the syringe, sterile

features

- in set with needle alongside the syringe
- transparent barrel allows full visual control of content, green contrasting plunger
- luer nozzle placed centrally for 2 ml capacity, eccentric for 5, 10, 20, 50 ml capacity
- 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 (extended to 6 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 ml
- needle tube is made of smooth and durable stainless steel
- needle tip sharpened in three surfaces
- bevel type: LB/BL standard long bevel
- hubs coloured in accordance with ISO code
- non-toxic, non-pyrogenic
- latex-free, phthalate-free

indication

- 3-piece syringe for subcutaneous, intramuscular and intravenous infusions

REF	type	capacity	position of nozzle	needle size	needle colour	intermediate packaging	bulk packaging
002ML-3CZ-SN	luer	2 ml	centric	0,6mm x 30mm	deep blue	100 pcs	30 x 100 pcs
005ML-3CZ-SN	luer	5 ml	eccentric	0,7mm x 30mm	black	100 pcs	24 x 100 pcs
010ML-3CZ-SN	luer	10 ml	eccentric	0,8mm x 40mm	deep green	100 pcs	16 x 100 pcs
020ML-3CZ-SN	luer	20 ml	eccentric	0,8mm x 40mm	deep green	50 pcs	16 x 50 pcs
050ML-3CZ-SN	luer	50 ml	eccentric	0,8mm x 40mm	deep green	25 pcs	16 x 25 pcs



endotracheal tube

cuffed, sterile

features

- made of flexible PVC
- equipped with lateral Murphy eye and radiopaque line over the entire tube length
- graduated every 1 cm, double depth marker to control the position of the tube
- low-pressure, high-volume cuff
- tube size marked in 4 places (on the connector, on the pilot balloon and in two places on the tube body)
- detachable connector with an outer diameter of 15 mm
- pilot balloon with LOT and size indication
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- for both oral and nasal intubation
- inserted into the trachea to prevent airway obstruction and respiratory failure

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



bulk packaging:
10 x 20 pcs



reinforced endotracheal tube

cuffed, sterile

features

- made of flexible PVC
- reinforcing within the wall of the entire tube
- equipped with lateral Murphy eye and radiopaque line over the entire tube length
- graduated every 1 cm, double depth marker to control the position of the tube
- tube size marked in 4 places (on the connector, on the pilot balloon and in two places on the tube body)
- indissociable connector with an outer diameter of 15 mm
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- for both oral and nasal intubation
- inserted into the trachea to prevent airway obstruction and respiratory failure
- for intubation of the patient in an unusual position, with a high risk of kinking the endotracheal tube

REF	size	intermediate packaging
RIMZP-30	I.D. (mm) 3.0	10 pcs
RIMZP-35	I.D. (mm) 3.5	10 pcs
RIMZP-40	I.D. (mm) 4.0	10 pcs
RIMZP-45	I.D. (mm) 4.5	10 pcs
RIMZP-50	I.D. (mm) 5.0	10 pcs
RIMZP-55	I.D. (mm) 5.5	10 pcs
RIMZP-60	I.D. (mm) 6.0	10 pcs
RIMZP-65	I.D. (mm) 6.5	10 pcs
RIMZP-70	I.D. (mm) 7.0	10 pcs
RIMZP-75	I.D. (mm) 7.5	10 pcs
RIMZP-80	I.D. (mm) 8.0	10 pcs
RIMZP-85	I.D. (mm) 8.5	10 pcs
RIMZP-90	I.D. (mm) 9.0	10 pcs
RIMZP-95	I.D. (mm) 9.5	10 pcs
RIMZP-100	I.D. (mm) 10.0	10 pcs



bulk packaging:
10 x 10 pcs



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60139535 0001

Report No.: 26300232 017

Manufacturer: ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products: (see attachments for products and sites included)
Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

Rafal Byczkowski



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/6, Rev. 0

**Attachment to
Certificate**

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

Manufacturer: **ZARYS International Group**
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs
(with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges
(with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls
(with or without X-ray thread)
- Sterile and non-sterile gauze rolls
(with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
(with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

Notified Body



Rafal Byczkowski



Date: 2019-05-27

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 0

**Attachment to
Certificate**

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

Manufacturer: ZARYS International Group
Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Date: 2019-05-27

Notified Body


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Certificate**

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ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Date: 2019-05-27

Notified Body


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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


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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

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Spolka z ograniczona odpowiedzialnoscia,
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

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

Activity: Production

Date: 2019-05-27

Notified Body

Rafal Byczkowski



Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 1023663-1

Organization: ZARYS International Group
Spółka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Scope: Design and development, manufacture and distribution of sterile:
surgical kits, procedure sets, surgical drapes and sets of surgical
drapes.
Manufacture and distribution of sterile and non-sterile disposable
medical devices and non-sterile reusable medical devices.
Distribution of in-vitro medical devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the above mentioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10



Rafał Byczkowski
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Tillystraße 2 · 90431 Nürnberg · Germany