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

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- latex-free
- EO sterilized
- packaging: 1 pc./foil

inication

• 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

• 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

• 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
NUD	210 cm +/- 5%



bulk packaging: 50 x 1 pc.



SANVIflon

I.V. cannula, sterile

features

- needle (stylet) made of stainless steel with back-cut blade
- cannula catheter made of Teflon (FEP), equipped with 4 radiopaque lines
- cannula equipped with wings and hand-closed cap of the upper port colour coded according to size
- · handle that allows you to insert with one hand
- valve that prevents blood leakage to outside after inserting the cannula into the vessel
- flashback chamber secured with a luer lock cap
- available in various sizes from 14 G to 26 G
- · single-use
- · latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc. hard blister (PVC + lacquered paper) with a colour print in accordance with the colour identification of the size

indication

for cannulation of intravenous, peripheral vessels to:

- · multiple injections of intravenous drugs
- intravenous infusion of solutions and parenteral nutrition suitable for peripheral veins
- maintain the patient's hydration and / or reduce dehydration if the patient is unable to take sufficient fluid orally
- blood transfusions and blood-like preparations
- ensuring vascular access in the event of the need for rapid drug delivery,
- especially during diagnostic and therapeutic procedures



REF	size [G]	size [mm]	colour	flow rate [ml/min]	intermediate packaging
KDF-06-19	26 x ¾"	0,6 x 19	violet	17	100 pcs
KDF-07-19	24 x ¾"	0,7 x 19	yellow	23	100 pcs
KDF-09-25	22 x 1"	0,9 x 25	blue	36	100 pcs
KDF-11-32	20 x 11/4°	1,1 x 32	pink	56	100 pcs
KDF-13-45	18 x 1¾"	1,3 x 45	green	90	100 pcs
KDF-15-45	17 x 1¾"	1,5 x 45	white	142	100 pcs
KDF-17-45	16 x 1¾"	1,7 x 45	grey	200	100 pcs
KDF-20-45	14 x 1¾"	2,0 x 45	orange	305	100 pcs



bulk packaging 10 x 100 pcs

SANVIflon S

I.V. cannula without port, sterile

features

- needle (stylet) made of stainless steel with back-cut blade
- cannula catheter made of Teflon (FEP), equipped with 4 radiopaque lines
- cannula equipped with coloured fixing wings, without upper port
- handle that allows you to insert with one hand
- valve that prevents blood leakage to outside after inserting the cannula into the vessel
- flashback chamber secured with a luer lock cap
- available in two sizes: 24 G and 26 G
- single-use
- latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc. hard blister (PVC + lacquered paper) with a colour print in accordance with the colour identification of the size

indication

for cannulation of intravenous, peripheral vessels to:

- multiple injections of intravenous drugs
- intravenous infusion of solutions
- maintain the patient's hydration and / or reduce dehydration if the patient is unable to take sufficient fluid orally
- ensuring vascular access in the event of the need for rapid drug delivery, especially during diagnostic and therapeutic procedures



REF	size [G]	size [mm]	colour	flow rate [ml/min]	intermediate packaging	_
KDFS-06-19	26 x ¾"	0,6 x 19	violet	17	100 pcs	i
KDFS-07-19	24 x ¾"	0,7 x 19	yellow	23	100 pcs	



bulk packaging: 10 x 100 pcs



DRESSING TAPE

features

- made of hydrophobic non-woven
- · covered with hypoallergenic acrylic glue
- 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
- flexible, conforms to the body's contours, guarantees freedom of movement
- backing layer made of silicone paper
- · backing paper with metric scale facilitates the division of the tape and precise, painless and efficient application
- packed in a cardboard box a dispenser that allows dosing without removing the tape from the packaging

indication

- · stabilization, protection and fixation of primary, non-adhesive dressings, applied directly to wounds and skin damages
- stabilization, protection and fixation of drains, catheters, medical tubes











adhesive non-woven dressing tape

elastopor



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non-steri	I۲
HOTT SCCT	-

REF	dimensions	packaging unit box	bulk packaging carton
806009	2,5 cm x 10 m	1 pc.	200 pcs
806010	5 cm x 10 m	1 pc.	100 pcs
806011	10 cm x 10 m	1 pc.	50 pcs
806012	15 cm x 10 m	1 pc.	50 pcs
806013	20 cm x 10 m	1 pc.	25 pcs
806014	25 cm x 10 m	1 pc.	25 pcs
806015	30 cm x 10 m	1 pc.	25 pcs



intersection of backing paper









elastopor E



non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
* 806009E	2,5 cm x 10 m	1 pc.	200 pcs
806010E	5 cm x 10 m	1 pc.	100 pcs
806011E	10 cm x 10 m	1 pc.	50 pcs
806012E	15 cm x 10 m	1 pc.	50 pcs
806013E	20 cm x 10 m	1 pc.	25 pcs
806014E	25 cm x 10 m	1 pc.	25 pcs
806015E	30 cm x 10 m	1 pc.	25 pcs



wavy intersection of backing paper



available on request

dicoNEX

single-use catheter syringe, 3-part, sterile

features

- transparent barrel allows full visual control of content
- green contrasting plunger
- two luer connectors attached
- 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
- nozzle cut at 90°
- catheter nozzle secured with cap
- name of syringe and manufacturer's logo placed on barrel
- extended graduation
- clear, legible and permanent black graduation facilitating dosage
- graduated every 1 ml
- single-use
- · non-pyrogenic
- · latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- 3-piece syringe with catheter nozzle
- intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient

REF	type		of nozzle	intermediate packaging
050ML-3CZ-CEV	V-BL catheter tip	50/60 ml	centric	25 pcs





dicoNEX

single-use catheter syringe, 3-part, sterile

features

- 3-piece syringe with centrally located nozzle for catheter
- two luer connectors attached
- made of polypropylene
- transparent barrel allows full visual control of content
- white contrasting plunger
- 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
- nozzle cut at 45°
- name of syringe and manufacturer's logo placed on barrel
- clear, legible and permanent black graduation facilitating dosage
- graduated every 2 ml
- latex-free, phthalate-free
- single-use
- EO sterilized
- packaging: 1 pc./paper-foil

- 3-piece syringe with catheter nozzle
- intended for drawing up and administering of medicines/liquids to patient and collecting body fluid samples from patient

٠	REF	type	capacity		intermediate packaging
i	100ML-3CZ-CEW-BL	catheter tip	100 ml	centric	25 pcs





DISPOSABLE MEDICAL BEDDING SET

non-sterile

features:

130

- 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





bulk packaging: 25 x 1 set







DISPOSABLE ABSORBENT UNDERPAD

non-sterile

features:

- composed of five layers:
- laminate + 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



- 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

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- · non-pyrogenic, non-toxic
- EO sterilized
- packaging: 1 pc./paper-foil

- 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





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

- 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





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







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)
- indissiociable connector with an outer diameter of 15 mm
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

- for both oral and nasal intubation
- $\bullet\,$ 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







easyFLOW LINE

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
P1500-BF	transparent	150 cm	50 pcs
PB1500-BF	amber	150 cm	50 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

indicatior

• device used for the administration of blood and blood products







SELF-ADHESIVE DRESSINGS WITH ABSORBENT PAD

features

- $\bullet \ self-adhesive \ dressings \ with \ centrally \ situated \ absorbent \ pad, \ made \ of \ hydrophobic \ non-woven, \ covered \ with \ acrylic \ glue$
- 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



sterile

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



sterile

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

- 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	51cmx76cm	1 nc	50 x 1 pc

tiemann catheter

sterile

features

- made of soft and flexible PVC, that is resistant to bending and kinking
 atraumatic, soft rounded, special tip facilitating insertion of the catheter to the bladder
- tip with two lateral eyes with smooth edges
- cone-shaped angled tip, bent at an angle of 45°
- transparent tube allowing visual inspection of excreted urine
- colour-coded connectors for size recognition, numerical size identification on the packaging
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

• to drain urine from the bladder in the case of a narrowed urethra

REF	length	size	colour	intermediate packaging	bulk packaging
CT-08-40	400 mm	CH 8	blue	60 pcs	10 x 60 pcs
CT-10-40	400 mm	CH 10	black	60 pcs	10 x 60 pcs
CT-12-40	400 mm	CH 12	white	50 pcs	10 x 50 pcs
CT-14-40	400 mm	CH 14	green	50 pcs	10 x 50 pcs
CT-16-40	400 mm	CH 16	orange	50 pcs	10 x 50 pcs
CT-18-40	400 mm	CH 18	red	40 pcs	10 x 40 pcs
CT-20-40	400 mm	CH 20	yellow	40 pcs	10 x 40 pcs
CT-22-40	400 mm	CH 22	purple	40 pcs	10 x 40 pcs
CT-24-40	400 mm	CH 24	dark blue	40 pcs	10 x 40 pcs





urine bag

sterile

- latex-free 2000 ml bag made of 0,22 mm thick PVC (double wall)
- double sealed PVC for maximum protection against tearing the bag
- effective non-return valve
- tight T-valve, that can be easily operated with one hand
- connecting tubing with universal stepped connector, standard tubing length 90 cm and 150 cm
- tubing made of material that is resistant to bending and kinking and which ensures a free and effective urine outflow
- precise, easy-to-read scale (every 100 ml), adequate for diuresis measurement
- strengthened holes for hanging, matching standard hangers
- white back wall making urine easy to notice
- single-use
- · latex-free
- EO sterilized
- packaging: 1 pc./foil

- for 24-hour extracorporeal collection of urine and other body fluids
- maximum time of use 24 hours

REF	capacity	length of tubing	intermediate packaging
WMD2000-90	2000 ml	90 cm	10 pcs
WMD2000-150	2000 ml	150 cm	10 pcs



bulk packaging:



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





catheter mount with double swivel elbow connector

sterile

features

- smooth bore type made of medical PVC
- expandable type made of high quality PE, EVA
- universal patient connection: 22M/15F
- ventilation device side connector: 15M or 22F
- $\bullet \ \ \text{expandable version characterized by shape memorizing}$
- 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: smooth bore and expandable
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

- 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	type	connection	length (without connectors)	intermediate packaging
PM-15-G	smooth bore (not expandable)	22M/15F-15M	15 cm	10 pcs
PM-22-G	smooth bore (not expandable)	22M/15F-22F	15 cm	10 pcs
PMR-15-K	expandable	22M/15F-15M	8-15 cm	10 pcs
PMR-22-K	expandable	22M/15F-22F	8-15 cm	10 pcs



oxygen mask

with tubing, sterile

features

- made of transparent, non-toxic PVC
- made of transparent, non-toxic rvc
 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

50

- 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%	М
MTS-L	210 cm +/- 5%	L
MTS-XL	210 cm +/- 5%	XL





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

 $\bullet\,$ 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%	М
MTW-L	210 cm +/- 5%	L
MTW-XL	210 cm +/- 5%	XL







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

Rafal Byczkowski

Notified Body

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.: Report No.: DD 60139535 0001 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

TÜVRheinlar

rinziorung

Rafal Byczkowski



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 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



Rafal Byczkowski



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 3/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 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

Notified Body

TÜVRheinlan

Rafal Byczkowski



TÜVRheinland

tinzierung

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 4/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 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 cannulla 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

Rafal Byczkowski



Meierungs

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 5/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 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

Rafal Byczkowski



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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 6/6, Rev. 0

Attachment to Certificate

Registration No.:

DD 60139535 0001 26300232 017

Manufacturer:

Report No.:

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

TÜVRheinland

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, manu acture and distribution of sterile:

surgical kits, procedure sets, surgical drapes and sets of surgical

drapes.

Wajid A

Manufacture and distribution of sterile and non-sterile disposable

medical devices and non sterile reusable medical devices.

Distribution of in-vitto medical devices.

The Confication Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quarty management system for medical devices.

Process the 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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