



adhesive non-woven tape

SOFTplast



non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
SNW12505W	1,25 cm x 5 m	24 pcs	30 x 24 pcs
SNW25005W	2,5 cm x 5 m	12 pcs	30 x 12 pcs
SNW50005W	5 cm x 5 m	6 pcs	30 x 6 pcs
SNW12509W	1,25 cm x 9,14 m	24 pcs	30 x 24 pcs
SNW25009W	2,5 cm x 9,14 m	12 pcs	30 x 12 pcs
SNW50009W	5 cm x 9,14 m	6 pcs	30 x 6 pcs



adhesive silk tape

SILKplast



non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
SS12505W	1,25 cm x 5 m	24 pcs	30 x 24 pcs
SS25005W	2,5 cm x 5 m	12 pcs	30 x 12 pcs
SS50005W	5 cm x 5 m	6 pcs	30 x 6 pcs
SS12509W	1,25 cm x 9,14 m	24 pcs	30 x 24 pcs
SS25009W	2,5 cm x 9,14 m	12 pcs	30 x 12 pcs
SS50009W	5 cm x 9,14 m	6 pcs	30 x 6 pcs





SELF-ADHESIVE NON-WOVEN DRESSINGS

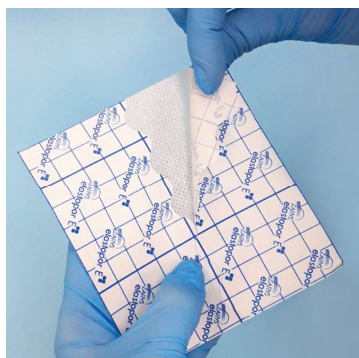
DRESSING TAPE

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




made of
hydrophobic
non-woven


air permeable
structure


possibility of
cutting


white
colour

adhesive non-woven dressing tape

elastopor



non-sterile

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.	200 pcs
806011	10 cm x 10 m	1 pc.	5 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	3 cm x 10 m	1 pc.	25 pcs



straight
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.	200 pcs
806011E	10 cm x 10 m	1 pc.	50 pcs
806012E	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.	2 pcs



wavy
intersection
of backing paper

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.



easyFLOW IS

infusion set, sterile

features

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

indication

- device for fluid transfer in infusion therapy

REF	version		
IS	with phthalates	bulk packaging: 250 pcs	BESTSELLER
IS-BF	without phthalates		



extension tube for infusion pump

sterile

features

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

indication

- device used to extend infusion line

REF	colour of tube	length	intermediate packaging
P450-BF	transparent	45 cm	50 pcs
P1500-BF	transparent	150 cm	50 pcs
PB1500-BF	amber	150 cm	50 pcs

bulk packaging:
24 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



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
- 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
 - 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
- 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	capacity	intermediate packaging	bulk packaging
002ML-3CZ-BL	2 ml	100 pcs	30 x 100 pcs
005ML-3CZ-BL	5 ml	100 pcs	24 x 100 pcs
010ML-3CZ-BL	10 ml	100 pcs	16 x 100 pcs
020ML-3CZ-BL	20 ml	50 pcs	16 x 50 pcs
050ML-3CZ-BL	50 ml	25 pcs	16 x 25 pcs



BESTSELLER



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 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	capacity	colour of plunger	intermediate packaging	bulk packaging
003ML-3CZ-LL-BL	3 ml	green	100 pcs	30 x 100 pcs
005ML-3CZ-LL-BL	5 ml	green	100 pcs	24 x 100 pcs
010ML-3CZ-LL-BL	10 ml	green	100 pcs	16 x 100 pcs
020ML-3CZ-LL-BL	20 ml	green	50 pcs	16 x 50 pcs
030ML-3CZ-LL-BL	30 ml	green	50 pcs	16 x 50 pcs
050ML-3CZ-LL-BL	50 ml	green	25 pcs	16 x 25 pcs

amber type

050ML-3CZ-LL-B-BL	50 ml	white	25 pcs	16 x 25 pcs
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vaginal speculum

cusco type, sterile

features

- both blades made of transparent polystyrene
- locking bolt made of polyethylene
- perfectly smooth and streamlined edges
- colour coded bolts depending on the size
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

indication

- device designed for gynecological examination of the cervix and vagina

REF	width	colour	size
WG-XXS	16 mm	yellow	XXS
WG-XS	20 mm	white	XS
WG-S	24 mm	blue	S
WG-M	26 mm	red	M
WG-L	30 mm	green	L



bulk packaging:
100 pcs



BESTSELLER



dicoSPIKE

withdrawal cannula, sterile

features

- ergonomic design enables easy handling
- sharp spike enables hermetic and secure connection
- possibility of collecting medicines from packages of various capacities
- hermetic self-locking cap that closes the connector to provide maximum protection against contamination
- reliable protection against microbial contamination by using a 1,2 µm air filter
- available in version with bacterial and particle filter 5 µm
- compatible with luer and luer lock connectors
- latex-free, phthalate-free
- PVC-free
- non-pyrogenic
- single-use
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- device designed for medicine withdrawal from multi-dose vials and bottles of various capacities

REF	type of filter	colour	intermediate packaging
CPHZ	with bacterial filter 1,2 µm	green	25 pcs
CPHN	with bacterial filter 1,2 µm and particle filter 5 µm	blue	25 pcs



bulk packaging:
16 x 25 pcs



BESTSELLER



surgical suction set

with Yankauer cannula, standard, sterile

CANNULA

- completely transparent for full possibility of observing the sucked secretion
- light and perfectly balanced handle ensures high comfort of work and reduces hand fatigue
- perfectly smooth inner surface prevents blocking or retaining the sucked content, ensuring correct and optimal flow
- cannula with double bend of curvature
- four lateral eyes, which prevent the tip from sticking to the tissues and one central opening
- universal stepped connector ensures tight connection with a wide range of suction connecting tubes

TUBE

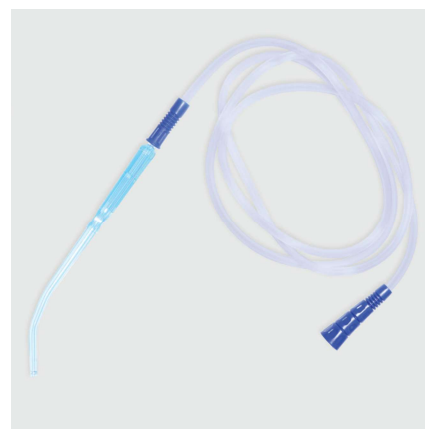
- made of soft and flexible PVC
- along the tube a special longitudinal reinforcement to prevent bending and sucking of the tube
- perfectly smooth inner surface of tube prevents the sucked content from settling on the walls, ensuring correct and optimal flow
- connector type funnel-funnel cut-to-fit with the possibility of cutting in the marked places of the connector and matching to any type of medical suction device (for the diameter of 8 mm to 18 mm)
- funnel connector equipped with a special bending system, enabling convenient manipulation of the tube
- tube connectors compatible with the standard suction cannulas, enabling their reliable, effective and tight connection

features

- available with or without suction control
- single-use
- latex-free
- EO sterilized
- packaging: 1 set/double packaging: internal- foil, external- paper-foil

indication

- evacuating secretions and body fluids from the operating field in general surgery



REF	size of cannula/ size of tube	length of tube	version
ZO-212400104	CH 21 / CH 24	210 cm	without suction control, funnel-funnel
ZO-212400114	CH 21 / CH 24	210 cm	with suction control, funnel-funnel
ZO-402423104	CH 21 / CH 24	400 cm	without suction control, funnel-funnel
ZO-402423114	CH 21 / CH 24	400 cm	with suction control, funnel-funnel
ZO-2124001041	CH 21 / CH 24	210 cm	without suction control, funnel-funnel cut-to-fit
ZO-2124001141	CH 21 / CH 24	210 cm	with suction control, funnel-funnel cut-to-fit



bulk packaging:
50 x 1 set

PE gloves

non-sterile

features

- made of polyethylene
- coarse surface and tear-resistant weld
- ambidextrous
- elongation min. 130%, tensile strength min. 10 MPa
- approved for contact with food
- single-use
- non-sterile
- packaging: 100 pcs/foil bag enabling individual removal of gloves

indication

- intended for use as a contribution to other gloves (double-gloving) and for minimally invasive procedures such as drug preparation, feeding the patient

REF	size	length
RF-M	M (women)	280 mm
RF-L	L (men)	300 mm



bulk packaging:
100 x 100 pcs



PE apron

non-sterile

features

- made of polyethylene
- transparent
- worn around the neck, tied at the back using straps
- single-use
- non-sterile
- packaging: 1 pc./foil

indication

- intended for medical staff as an additional protection in wet procedures, such as preparing medicines, washing the patient, feeding the patient

REF	length/ width	intermediate packaging
FF-71x116	116 cm / 71 cm	100 pcs
FF-71x180	180 cm / 71 cm	100 pcs



bulk packaging:
10 x 100 pcs



dual-limb breathing circuit

sterile

features

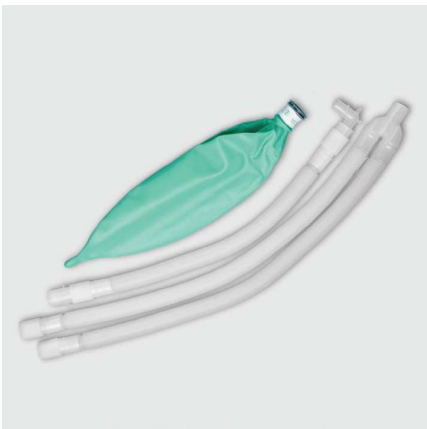
- made of high quality EVA material, without PVC
- 15F/22M and 22F universal connector fits compatible products and devices for mechanical ventilation or anesthesia machine
- expandable arms with maximum length of 160 cm
- adjustable length of circuit enabling adjustment of length of respiratory system and optimization of dead space
- equipped with latex-free breathing bag: 3l (for adults) or 1l (for children)
- additional expandable tube, length: 100 cm
- elbow with luer lock port
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

indication

- for patient's mechanical ventilation
- it enables transporting breathing mixture from equipment (ventilator, anesthesia machine) to respiratory protection device (e.g. tracheal tube, tracheostomy mask) and vice versa

REF	purpose	capacity of bag
OBWD-1601L	for children	1 liter
OBWD-1603L	for adults	3 liters


bulk packaging:
40 x 1 pc.



catheter mount/double swivel connector

sterile

features

- standard version made of medical PVC
- expandable version made of high quality EVA material, PVC-free and phthalate-free
- 22M/15F - 15M universal connector fits compatible products
- expandable version characterized by shape memorizing and by the ability to control the position of the connector
- double swivel elbow connector
- port for suctioning and bronchoscope secured with a stopper
- available in versions: standard and expandable
- single-use
- latex-free
- EO sterilized
- packaging: 1 pc./paper-foil

indication

- used to connect the tracheostomy tube or endotracheal tube with the breathing circuit of the ventilation device
- provides greater mobility and rotation of the connection, increasing patient comfort and safety

REF	version	length
PM-15	standard	15 cm
PMR-15	expandable	9-18 cm


bulk packaging:
250 x 1 pc.



endotracheal tube

cuffed, sterile

features

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

indication

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

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



bulk packaging:
10 x 20 pcs



reinforced endotracheal tube

cuffed, sterile

features

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

indication

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

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



bulk packaging:
10 x 10 pcs



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

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

Products included:

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

Date: 2019-05-27

Notified Body

Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/6, Rev. 0

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Spolka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

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

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/6, Rev. 0

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

Products included:

For the following medical devices the scope covers
only the aspects of manufacture concerned with
securing and maintaining sterile conditions:

- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

For the following medical devices the scope covers
only the aspects of manufacture concerned with
securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Date: 2019-05-27

Notified Body


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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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

Notified Body

Date: 2019-05-27


Rafal Byczkowski





SANVIflon premium I.V. Cannula TD-15

attachment No. 3
point 2 pp. 2.3

edition I
2020.08.28

page 1/1

MANUFACTURER: ZARYS International Group sp. z o.o. sp.k.

ADDRESS: ul. Pod Borem 18, 41-808 Zabrze, Poland, phone +48 32 376 07 00-02, 06, fax. +48 32 370 38 08

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



FEATURES:

- needle (stylet) made of stainless steel with back-cut blade
- cannula catheter made of polyurethane (PUR), equipped with 6 radiopaque lines
- cannula equipped with coloured suturable wings and a self-closing cap of the upper port colour coded according to size
- handle that allows you to insert with one hand
- hydrophobic filter 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 24 G
- single-use
- latex-free
- phthalate-free
- EO sterilized
- packaging: 1 pc. – hard blister (PVC+TYVEC) with a colour print in accordance with the colour identification of the size

SIZE AND REFERENCE

CATALOGUE NUMBER	SIZE [G]	SIZE [mm]	COLOUR	FLOW RATE [ml/min]	INTERMEDIATE PACKAGING	BULK PACKAGING
KDP-07-19	24 x ¾"	0,7 x 19	yellow	23	100 pcs	10 x 100 pcs
KDP-09-25	22 x 1"	0,9 x 25	blue	36	100 pcs	10 x 100 pcs
KDP-11-32	20 x 1¼"	1,1 x 32	pink	56	100 pcs	10 x 100 pcs
KDP-13-45	18 x 1¾"	1,3 x 45	green	90	100 pcs	10 x 100 pcs
KDP-15-45	17 x 1¾"	1,5 x 45	white	142	100 pcs	10 x 100 pcs
KDP-17-45	16 x 1¾"	1,7 x 45	grey	200	100 pcs	10 x 100 pcs
KDP-20-45	14 x 1¾"	2,0 x 45	orange	305	100 pcs	10 x 100 pcs

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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1 / 2