

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	length of tube	connector
ZO-212400104	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-212400114	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-402423104	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-402423114	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-2124001041	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit
ZO-2124001141	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit



bulk packaging:
50 x 1 set



3. Remove the paper protection on the outer side of the dressing starting from the cut.



4. Put the notes on the tape to describe the dressing and apply it on the dressing without covering the wound/ the place of needle insertion.

elastoDERM F-IV

IV cannula dressing, with “frame” application type

REF	dimensions	shape	indication	packaging unit paper-paper	bulk packaging box
812006	6 cm x 7 cm		- fixing and securing peripheral cannulas in adults - securing cannulas inserted into central veins	1 pc.	100 x 1 pc.

with the tape to describe the dressing

elastoDERM IV

IV cannula dressing, with “three-stage” application type

REF	dimensions	shape	indication	packaging unit paper-paper	bulk packaging box
811301	5,8 cm x 8 cm		- fixing and securing peripheral cannulas in adults	1 pc.	100 x 1 pc.

with the tape to describe the dressing

elastoDERM PAD

dressing with central absorbent pad, with “three-stage” application type

REF	dimensions	shape	indication	packaging unit paper-paper	bulk packaging box
802012	6 cm x 7 cm		- protection of post-operative wounds and stitches	1 pc.	100 x 1 pc.
802014	9 cm x 10 cm			1 pc.	50 x 1 pc.
802015	9 cm x 15 cm			1 pc.	50 x 1 pc.
802016	10 cm x 20 cm			1 pc.	50 x 1 pc.
802018	10 cm x 25 cm			1 pc.	50 x 1 pc.



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
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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.



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

Registration No.: DD 60139535 0001

Report No.: 26300232 017

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

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

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

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

Rafal Byczkowski



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

Date: 2019-05-27

Notified Body

Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/6, Rev. 0

**Attachment to
Certificate**

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

Manufacturer: ZARYS International Group
Spolka z ograniczoną odpowiedzialnością,
spółka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Polska

Products included:

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

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

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

Notified Body

Date: 2019-05-27


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/6, Rev. 0

**Attachment to
Certificate**

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

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

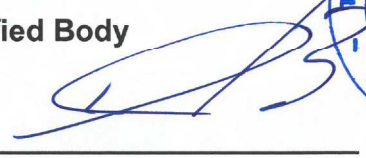
Products included:

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

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

Date: 2019-05-27

Notified Body


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 6/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

Activity: Production

Notified Body

Date: 2019-05-27


Rafal Byczkowski



Certificate

Quality Management System
EN ISO 13485:2016



Registration No.: SX 1023663-1

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

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

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

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10



Rafał Byczkowski
TR LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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