

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 |
|-------------------|-----------|----------|---------|-------|--------|-------------|



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.



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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.



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. |



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 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
- 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

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 | 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 |



bulk packaging:
10 x 10 pcs

oropharyngeal airway/guedel airway

sterile

features

- made of high quality PE (polyethylene), free of PVC
- distinctive anatomical curve of airway tube allows for the opening of the upper respiratory tract and the free flow of anaesthetic gases, air
- colour coded sizes
- numeric marking of the size on the airway
- single-use
- latex-free, phthalate-free
- EO sterilized
- packaging: 1 pc./foil

indication

- used during artificial ventilation procedures to ensure the airway patency
- as a tool for paramedic to assist in the management of a casualty's airway which increases the effectiveness of the rescue operation
- facilitates the stabilization of the endotracheal tube and protects it against biting

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



bulk packaging:
10 x 50 pcs



air cushion anaesthetic mask

non-sterile

features

- due to the high quality of materials used, ventilation is conducted in an atraumatic and safe way for the patient
- anatomically shaped inflatable cuff, ensures perfect tightness of the mask with minimal pressure
- device, when applied to the face, tightly covers the patient's mouth and nose without compressing the eyes
- clear shell provides continuous visual observation of the patient
- colour-coded retaining rings, easy for size recognition
- retaining ring can be removed when it is not needed
- full size range allows to properly choose the size of the mask depending on the age of the patient
- all sizes are equipped with inflatable check valve to adjust air amount for best cushion fitting auto patient's face
- single-use
- latex-free, phthalate-free
- non-sterile
- packaging: 1 pc./foil

indication

- intended for the administration of a gas mixture coming through devices for artificial ventilation
- enables performing medical procedures including artificial ventilation, administration of anesthetic gas and carrying out emergency treatment of an unconscious patient

| REF | size | age of patient/size | colour |
|-------|------|---------------------|--------|
| MAP-0 | 0 | neonate | - |
| MAP-1 | 1 | infant | - |
| MAP-2 | 2 | pediatric | yellow |
| MAP-3 | 3 | adult S | green |
| MAP-4 | 4 | adult M | red |
| MAP-5 | 5 | adult L | blue |
| MAP-6 | 6 | adult XL | orange |



bulk packaging:
100 x 1 pc.






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. |



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

Registration No.: DD 60139535 0001

Report No.: 26300232 017

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

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

Expiry Date: 2024-05-27

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

Effective Date: 2019-06-09

Date: 2019-05-27

Notified Body

Rafal Byczkowski



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

Notified Body



Date: 2019-05-27


Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 0

**Attachment to
Certificate**

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

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

Products included:

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

Date: 2019-05-27

Notified Body


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60139535 0001

Report No.: 26300232 017

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

Products included:

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

Date: 2019-05-27

Notified Body


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60139535 0001

Report No.: 26300232 017

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

Products included:

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

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

Notified Body



Date: 2019-05-27


Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Products included:

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

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

Notified Body



Date: 2019-05-27

Rafal Byczkowski

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60139535 0001
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

Date: 2019-05-27

Notified Body

Rafal Byczkowski



Certificate

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

Registration No.: SX 1023663-1

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

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

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

Report No.: 84947434 020

Effective date: 2020-06-10

Expiry date: 2023-06-08

Issue date: 2020-06-10



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