

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



3-way stopcock

sterile

features

- 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
- 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 | colour | intermediate packaging |
|--------|--------|------------------------|
| KT-002 | blue | 50 pcs |



bulk packaging:
20 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



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



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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