

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

Registration No.: DD 60117020 0001

Report No.: 26300232 005

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

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60100191 0001


Expiry Date: 2019-06-08

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: 2017-03-07

Notified Body

Date: 2017-03-07


Dr. K. Kluge



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. 2

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

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

Date: 2018-01-25

Notified Body

Maciej Sciera
Maciej Sciera



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

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: 2018-01-25

Notified Body

Maciej Sciera
Maciej Sciera



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

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: 2018-01-25

Notified Body

Maciej Sciera
Maciej Sciera



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

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

Date: 2018-01-25

Notified Body

Sciera
Maciej Sciera



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/6, Rev. 2

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

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: 2018-01-25

Notified Body

Maciej Sciera
Maciej Sciera



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 6/6, Rev. 2

**Attachment to
Certificate**

Registration No.: DD 60117020 0001
Report No.: 26300232 006

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

Sites included:

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

Activity: Production

Date: 2018-01-25

Notified Body

Maciej Sciera
Maciej Sciera



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

has established and applies a quality management system for medical devices
for the following scope:

**Production and distribution of disposable and reusable
medical devices and distribution of in-vitro medical devices
(see attachments for sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-11-07
Certificate Registration No.: SX 60120471 0001
An audit was performed. Report No.: 26300232 006
This Certificate is valid until: 2020-06-08

Certification Body



Date 2017-11-07


Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60120471 0001
Report No.: 26300232 006

Organization: ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

Scope:

Sites included:

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

Activity:

Production, storage and distribution of medical devices

Certification Body



Date: 2017-11-07

Maciej Sciera



insulin syringe

dicoSULIN sterile

features:

- with non-integrated needle 0,4 x 13 mm
- transparent barrel made of polypropylene allowing perfect visualization of the content
- sealing in the form of a double ring on a plunger stopper situated on the top of plunger
- smooth plunger sliding thanks to rubber sealing
- limitation flange securing against accidental removal of the plunger
- special design of the plunger stopper reduces the residual volume of the drug/liquid
- clear, legible and permanent black graduation facilitating dosage
- name of the syringe and manufacturer's logo placed on the barrel
- contrasting orange plunger for U-100 syringe, red for U-40 syringe
- volume 1 ml
- single-use
- non-pyrogenic, non-toxic
- latex-free
- DEHP-free
- EO sterilized
- packaging: 1 pc./blister-pack, 100 pcs/box

indication:

- 3-piece syringe for intravenous, intramuscular and hypodermic injections
- for insulin shots



ref.	number of units	volume	intermediate packaging	bulk packaging
IN-U40-1-BL	40	1 ml	100 pcs	32 x 100 pcs
IN-U100-1-BL	100	1 ml	100 pcs	32 x 100 pcs

insulin pen needle

dispoSULIN sterile

features:

- made of polypropylene, polyethylene and stainless steel
- triple-point needle blade allows easy and atraumatic skin penetration
- covering the needle with silicone lubricant reduces resistance during injection
- thin walls of the needle ensure easy flow of the drug and the right flow rate
- colored cap and the paper cover of the packaging make it easy to quickly recognize the size of the needle
- available in various sizes, allowing you to adapt to individual needs
- universal, compatible with all pen models
- single-use
- non-pyrogenic
- latex-free
- DEHP-free
- EO sterilized
- intermediate packaging: 100 pcs

indication:

- for subcutaneous injection
- dedicated for use with pre-filled pens (insulin pens)



ref.	size	colour	intermediate packaging	bulk packaging	
INP-033X12	0.33 mm x 12 mm	29G	pink	100 pcs	50 x 100 pcs
INP-030X08	0.30 mm x 8 mm	30G	yellow	100 pcs	50 x 100 pcs
INP-025X06	0.25 mm x 6 mm	31G	violet	100 pcs	50 x 100 pcs
INP-025X08	0.25 mm x 8 mm	31G	blue	100 pcs	50 x 100 pcs