

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

Registration No.: DD 60100191 0001

Report No.: 26300232 002

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

Products: (see attachment for products included)

Replaces Certificate, Registration No.: DD 60098972 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: 2015-03-02

Date: 2015-03-02

Notified Body



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. 1/4, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60100191 0001
Report No.: 26300232 002

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
- Sterile and non-sterile gauze swabs
(with or without X-ray thread)
- Sterile and non-sterile non-woven swabs
(with or without X-ray thread)
- Sterile and non-sterile lap sponges
(with or without X-ray thread)
- Non-sterile folded gauze
- Sterile paraffin gauze dressings
- Sterile oxygen masks
- Sterile non-rebreathe masks
- Sterile nebulizer masks
- Sterile Multi-Vent masks
- Sterile oxygen tubing
- Sterile nebulizer sets
- Sterile suction catheters
- Sterile three-way stopcocks
- Sterile infusion sets for single use
- Sterile extension tubes

Date: 2015-03-02

Notified Body

D. Swiatko



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60100191 0001
Report No.: 26300232 002

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

Products included:

- Sterile hypodermic needles
- Sterile endotracheal tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Sterile tracheostomy tubes
- Sterile laryngeal masks
- Sterile nasal oxygen cannulas
- Sterile urology catheters
- Sterile feeding tubes
- Sterile syringes for single use
- Sterile transfusion sets for single use
- 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 surgical suction sets
- Sterile surgical suction cannulas

Date: 2015-03-02

Notified Body

D. Swiatko



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/4, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60100191 0001
Report No.: 26300232 002

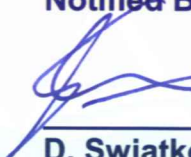
Manufacturer: ZARYS International Group
Spolka z ograniczona
odpowiedzialnoscia
spolka komandytowa
ul. Pod Borem 18
41-808 Zabrze
Poland

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

- Surgical gowns
- Incise films
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Surgical drapes
- Eye pads
- Transparent film dressings
- Foam dressings
- Vaginal speculums
- Urine bags
- Absorbent wound dressings
- Fluid collection pouches

Date: 2015-03-02

Notified Body



D. Swiatko



TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/4, Rev. 1

**Attachment to
Certificate**

Registration No.: DD 60100191 0001

Report No.: 26300232 003

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

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

- Nelaton catheters
- Cervical brushes
- Tongue depressors
- Intubation stylets
- Tracheal tube holders
- Guedel airways
- Suction tubes
- Alginate dressings
- Withdrawal cannulas

Notified Body



Date: 2016-02-02


M.Sc. M. Aihara