

**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  
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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**

**Attachment to  
Certificate**

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

**Manufacturer:** ZARYS International Group  
Spolka z ograniczona  
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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**



**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

**Date: 2016-02-02**

**Notified Body**

  
**M.Sc. M. Aihara**

