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, production and distribution of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes. Production 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 abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	84951712-170
Effective date:	2021-05-14
Expiry date:	2023-06-08
Issue date:	2021-05-14

Daniel Świątko
TÜV Rheinland LGA Products GmbH
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Digitally signed by Granaci Boris
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Reason: MoldSign Signature
Location: Moldova

Certificate

TÜVRheinland®

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

The scope of certification includes the following manufacturing sites:

No.	Facility	Scope
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Design, development and distribution of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes. Distribution of sterile and non-sterile disposable medical devices and non-sterile reusable medical devices. Distribution of in-vitro medical devices.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Storage, release and distribution of medical devices.
/03	ZARYS International Group Spółka z o.o. Produkcja sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Production of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes.

Report No.: 84951712-170
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Issue date: 2021-05-14

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.:	DD 1023663-1
Manufacturer:	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa ul. Pod Borem 18 41-808 Zabrze Poland
Products:	- 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 - Sterile endotracheal tubes - Sterile tracheostomy tubes

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.

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

EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

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

- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Venturi masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizers
- 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
- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles

Report No.: 84951712-170

Effective date: 2021-05-14

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TÜV Rheinland LGA Products GmbH Prüfstelle

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EC Certificate

TÜVRheinland®

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

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

- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves
- Sterile procedure kits

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

- Elastic bandages
- Adhesive cannula fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Alginate dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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EC Certificate

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Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

Manufacturer:

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

- Fluid collection pouches
- Nelaton catheters
- Vaginal speculums
- Cervical brushes
- Urine bags
- Enema bags
- Tongue depressors
- Oropharyngeal airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Cannula stoppers
- Umbilical cord clamps

Replaces EC Certificate, Registration No.: DD 60139535 0001

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TÜVRheinland
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Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 1023663-1

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

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	ZARYS International Group Spółka z o.o. sp.k. ul. Pod Borem 18 41-808 Zabrze Poland	Activity: Final inspection and release.
/02	ZARYS International Group Spółka z o.o. sp.k ul. Guido Henckela Donnersmarcka 1 41-808 Zabrze Poland	Activity: Final inspection and release.

Report No.: 84951712-170

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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