Certificate

Quality Management System EN ISO 13485:2016

Registration No. SX 1023663-1

Certificate Holder 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 sets, procedure kits, surgical drapes, sets of surgical

drapes, surgical gowns and knitted bandages. Production and distribution of sterile and non-sterile

disposable medical devices and non-sterile reusable medical

devices.

Distribution of in-vitro diagnostic 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.
 84965698-20

 Effective date
 2023-06-09

 Expiry date
 2026-06-08

 Issue date
 2023-06-06

 Replaces certificate SX 1023663-1 issued 2021-05-14

This certificate can be validated on https://www.certipedia.com

Daniel Świątko TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany





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Poland

The scope of certification also covers the following sites:

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

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