

Certificate

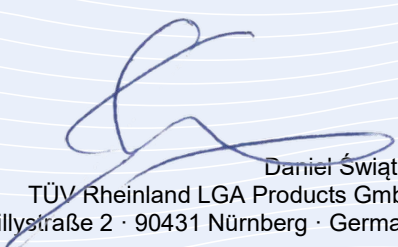
Quality Management System EN ISO 13485:2016

| | |
|--------------------|---|
| 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
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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

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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