

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 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 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.:	84984397-20
Effective date:	2025-12-11
Expiry date:	2026-06-08
Issue date:	2025-12-11
Replaces certificate SX 1023663-1 issued 2023-06-06	

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


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Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 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 medical devices.
/02	ZARYS International Group Spółka z o.o. sp.k. ul. Guido Henckela Donnersmarcka 1 41-807 Zabrze Poland	Storage, quality control, 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 sets, procedure kits, surgical drapes, sets of surgical drapes, surgical gowns and knitted bandages. Production of non-sterile disposable medical devices.
/04	ZARYS International Group Spółka z o.o. sp.k. ul. Ziemska 44 41-803 Zabrze Poland	Administration. Design and development and distribution of medical devices.

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