

# 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



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TÜV Rheinland LGA Products GmbH  
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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.

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