

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, manufacture and distribution
of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical
drapes.
Manufacture 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.: 84947434 020

Effective date: 2020-07-09

Expiry date: 2023-06-08

Issue date: 2020-07-09



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

No.	Facility	Scope
/01	ZARYS International Group Spółka z ograniczoną odpowiedzialnością, spółka komandytowa ul. Pod Borem 18 41-808 Zabrze Poland	Activity: Design and 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 Sp. z o.o. Sp. k. ul. Eiffel'a 15 44-105 Gliwice Poland	Activity: Storage, 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	Activity: Manufacture of sterile: surgical kits, procedure sets, surgical drapes and sets of surgical drapes.

Report No.: 84947434 020

Effective date: 2020-07-09

Expiry date: 2023-06-08

Issue date: 2020-07-09



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany