

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1436359-1
Certificate Holder: INFIMED Sp. z o.o.
Kabaty 1
34-300 Żywiec
Poland

Scope: Design and development, production, distribution, installation and servicing of surgical and treatment luminaires, luminaires for diagnosis, devices for patient positioning and transport with related equipment, medical furniture, modular room systems for operating theatre as well as software working in combination with related infrastructure for managing and integration of equipment and medical devices in operating room.

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.: 84978373-20
Effective date: 2025-01-31
Expiry date: 2028-01-30
Issue date: 2025-01-29
Replaces certificate SX 1436359-1 issued 2022-02-18

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



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