

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1436359-1

Organization: INFIMED Sp. z o.o.
ul. 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.

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