

Certificate

The Certification Body of **TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

Infimed Sp. z o.o. ul. Kabaty 1 34-300 Zywiec Poland

has established and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2019-02-13

Certificate Registration No.:

SX 60136721 0001

An audit was performed. Report No.: 26300455 001

This Certificate is valid until:

2022-01-31

Certification Body



Date 2019-02-13

Maciej Sciera

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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

SX 60136721 0001 26300455 001

Organization:

Infimed Sp. z o.o. ul. Kabaty 1 34-300 Zywiec 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

Certification Body



Date: 2019-02-13

