

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1023642-1

Organization: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
Poland

Scope: Design and development, manufacture, distribution and service of orthopaedic implants, non-active surgical instruments, medical drives and attachments, tourniquet control units.

Sterilization of medical devices by hydrogen peroxide.

Manufacture of orthopaedic implants using Selective Laser Melting (SLM) technology.

Manufacture of class III custom-made implantable 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.: 84955279-20
Effective date: 2022-02-04
Expiry date: 2024-04-12
Issue date: 2022-02-04



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