

Certificate

Certificate No.: MD 1023642-1-1

Manufacturer: **ChM sp. z o.o.**
Lewickie 3B
16-061 Juchnowiec Kościelny
Poland

REPs Facility ID: F004449

Certification criteria: ISO 13485:2016
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D, 21 CFR 821

Scope: Design and development, manufacture and distribution of non-sterile orthopedic implants and non-active non-sterile surgical instruments in the area of orthopaedics.

TÜV Rheinland[®]

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 84971449-30

Issue Date: 2024-04-16

Effective Date: 2024-04-18

Expiry Date: 2027-04-18



Certification officer: Rafał Byczkowski
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.