

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 0198 100 15173



Certificate Holder: **ChM Sp. z o. o.**
Lewickie 3B
16-061 Juchnowiec Kościelny
Poland

Scope: design and development, manufacture and distribution of:
orthopedic implants, dental implants with accessories, steel
surgical sutures, non-active and active medical devices;
sterilization of medical devices by hydrogen peroxide

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2018-04-19 until 2021-04-18.

2018-04-19

Grzegorz Guabka

TÜV Rheinland Polska Sp. z o.o.
ul. Komitetu Obrony Robotników 56, 02-146 Warszawa

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EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144424 0001

Report No.: 26300273 015

Manufacturer: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland

Products: (see attachment for products included)

Replaces EC Certificate, Registration No.: HD 60099942 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-11-19

Date: 2019-11-19

Notified Body

Rafal Byczkowski



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144424 0001
Report No.: 26300273 015

Manufacturer: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland

Products included, Class IIb:

- Bone nails (sterile and non-sterile)
- Bone pins (sterile and non-sterile)
- Bone screws (sterile and non-sterile)
- Bone plates (sterile and non-sterile)
- Bone staples (sterile and non-sterile)
- Fixation devices, internal, wire (sterile and non-sterile)
- Fixation devices, internal, spine, construct (sterile and non-sterile)
- Fixation devices, internal, hip, plate, compression (sterile and non-sterile)
- Fixation devices, internal, washer (sterile and non-sterile)
- Radial bone head prosthesis (sterile)
- Dentals implants (sterile)
- Abutments for dental implants (non-sterile)
- Steel surgical sutures (sterile)
- Interference polymer bone screws (sterile and non-sterile)

Notified Body

Date: 2019-11-19


Rafal Byczkowski



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60144424 0001
Report No.: 26300273 015

Manufacturer: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland

Products included, Class IIa:

- Bone drills (non-sterile)
- Bone cutters (non-sterile)
- Bone reamers (non-sterile)
- Bone tapes (non-sterile)
- Bone countersinks (non-sterile)
- Bone trephines (non-sterile)
- Guide wires for orthopaedic application (non-sterile)
- Trials (non-sterile)
- Cover screws (non-sterile)
- Healing caps (non-sterile)
- Drill bits (sterile)
- Medical drives (non-sterile)
- Tourniquet control units (non-sterile)

Date: 2019-11-19

Notified Body


Rafal Byczkowski



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland**

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

(see attachment for scope)

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: 2018-04-13
Certificate Registration No.: SX 60128456 0001
An audit was performed. Report No.: 26300273 009
This Certificate is valid until: 2021-04-12

Certification Body



Date 2018-04-13



M.Sc. M. Aihara

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 1

**Attachment to
Certificate
Registration No.:
Report No.:**

**SX 60128456 0001
84946854 050**

Organization:

**ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland**

Scope:

Design and development, manufacture and distribution of

- Orthopaedic implants
- Dental implants with accessories
- Steel surgical sutures
- 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.

Certification Body



Date: 2020-05-27

Rafal Byczkowski