EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023642-1

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

Products:
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)
- Interference polymer bone screws (sterile and non-sterile)

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.

Report No.: 84952558-30

Effective date: 2021-04-08

Expiry date: 2024-05-26

Issue date: 2021-04-08

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 1023642-1
Manufacturer:	ChM sp. z o.o. Lewickie 3b 16-061 Juchnowiec Kościelny Poland

Products included, class IIa:
- Bone drills (non-sterile)
- Bone cutters (non-sterile)
- Bone reamers (non-sterile)
- Bone taps (non-sterile)
- Bone countersinks (non-sterile)
- Bone trephines (non-sterile)
- Guide wires for orthopaedic application (non-sterile)
- Trials (non-sterile)
- Drill bits (sterile)
- Medical drives (non-sterile)
- Tourniquet control units (non-sterile)

Replaces EC Certificate, Registration No.: HD 60144424 0001

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