

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III



Registration No.: HZ 1023642-1

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

EUDAMED Single
Registration No.: N/A

Products: Class I devices, reusable surgical instruments:

- L091099 - Osteosynthesis Instruments, Reusable – Others
- L090402 - Chisels, Orthopaedic Surgery
- L090403 - Gouges, Orthopaedic Surgery
- L0903 - Mallets, Orthopaedic Surgery
- L091001 - Instruments For Insertion And Extraction Of Osteosynthesis
Devices
- L0916 - Orthopaedic Burs, Reusable
- L031401 - Retractors, General Surgery
- L0908 - Orthopaedic Traction, Brackets
- L091399 - Forceps, Orthopaedic Surgery - Others
- L090901 - Bone Cutting Forceps
- L090999 - Orthopaedic Surgery, Cutting Instruments – Others
- L091302 - Orthopaedic Rongeurs
- L090401 - Osteotomes, Orthopaedic Surgery
- L091202 - Files, Orthopaedic Surgery
- L031310 - Dissecting Forceps

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84946208-60

Effective date: 2020-12-15

Expiry date: 2025-04-29

Issue date: 2020-12-15



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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- L0902 - Elevators, Orthopaedic Surgery
- L091002 - Instruments For Osteosynthesis Devices, Preparation
- L091201 - Raspatories, Orthopaedic Surgery
- L010103 - Scalpel Handles
- L0102 - Surgical Knives
- L010412 - Scissors, Orthopaedic
- L010499 - Surgical Scissors - Others
- L0107 - Surgical Saws
- L0202 - Suture Needles
- L0205 - Needle Holders
- L031301 - Biopsy Forceps, General Surgery
- L031302 - Forceps, Dressing
- L031304 - Forceps, Grasping
- L031306 - Forceps, Hemostatic
- L031309 - Ligatures Passers
- L031399 - Forceps, General Surgery - Others
- L070801 - Forceps, Vascular
- L031402 - Spatulae, General Surgery
- L040802 - Specialized Forceps, Gastrointestinal
- L040901 - Abdominal Retractors
- L050901 - Uterine Curettes
- L050902 - Gynaecological Dilators And Retractors
- L050903 - Forceps, Gynaecological Surgery
- L059001 - Reusable Vaginal Specula
- L059003 - Gynaecological Hooks
- L060604 - Forceps, Prostate Gland
- L060699 - Urological Forceps – Others
- L070802 - Vascular Dilators

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- L080502 - Forceps, Lung
- L080602 - Thoracic Surgery Retractors
- L0901 - Bone Spoons And Curettes
- L091003 - Wire And Plates Scissors
- L091199 - Orthopaedic Prostheses Instruments, Reusable – Others
- L091101 - Orthopaedic Prostheses Extractors
- L9099 - Reusable Surgical Instruments – Others
- L110699 - Forceps, Neurosurgery – Others
- L110601 - Intervertebral Disc Rongeurs

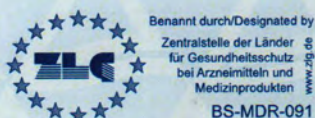
The scope of certification is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

Authorised representative(s): N/A



Certificate history		
Revision:	Description:	Issue date:
1	Initial.	2020-10-02
2	Change of certificate template.	2020-12-15

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