EU Certificate

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

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

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.

EU Certificate

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

TÜVRheinland®

Registration No.: HZ 1023642-1

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

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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