

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 1594091-1

Manufacturer: **Carl Martin GmbH**
Neuenkamper Str. 80-86
42657 Solingen
Germany

EUDAMED Single
Registration No.: DE-MF-000005066

Products: Products of class I, reusable surgical instruments:

- L0205 - Needle Holders
- L0901 - Bone Spoons and Curettes
- L0399 - General Surgery Instruments - Others
- L0904 - Osteotomes and Chisels
- L031399 - Forceps, General Surgery - Others
- L031199 - Probes and Stylets - Others
- L010499 - Surgical Scissors - Others
- L031308 - Surgical and Anatomic Tweezers
- L010101 - One-Piece Scalpels

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 version	2021-11-04

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.: 3340730-50

Effective date: 2021-11-04

Expiry date: 2026-06-29

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