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 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 Zertifizierungsstelle TÜVRheinland

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

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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.