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 1809678-1

Manufacturer: **Medartis AG**
Hochbergerstr. 60E
4057 Basel
Switzerland

EUDAMED Single Registration No.: CH-MF-000022291

Products: Products of class I, reusable surgical instruments:

L091099 - Osteosynthesis Instruments, reusable - other
L9099 - Surgical Instruments, reusable - other

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

Products of class IIa:

L091001 - Instruments for Insertion and Extraction of Materials for Osteosynthesis, reusable
Q010403 - Orthodontic Brackets and Buttons
V9012 - Non-Specialist Surgical Instruments and Kits, single-use
Z121305 - Motorised Orthopaedic Surgery System Instruments

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.: 3346648-50

Effective date: 2023-06-28

Expiry date: 2026-12-29

Issue date: 2023-06-28

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Roland Gruber
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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Registration No.: HZ 1809678-1

Manufacturer:

Medartis AG
Hochbergerstr. 60E
4057 Basel
Switzerland

Products of class IIb:

Osteosynthesis Devices, Devices for Tendon and and Ligament Synthesis
P091201 - Osteosynthesis Staples and Anchors
P091205 - Bone Fixation Plates
P091206 - Bone Fixation Screws, Tendon and Ligament Synthesis Screws

Software, CMX Portal
V92 - Not Otherwise Classified Devices – Others

Authorised representative(s):

Medartis GmbH
Am Gansacker 10
79224 Umkirch
Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial revision	2022-04-21
1	Scope, Products of class IIb, added V92 - Not Otherwise Classified Devices – Others	2023-05-31

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