EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: CH-MF-000030696)

Cendres+Métaux SA

Rue de Boujean 122
2501 Biel/Bienne
Switzerland

EU Authorized Representative: QualRep Services B.V., Utrechtseweg 310 – Bldg B42, NL-6812 AR Arnhem, The Netherlands

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-04-06	Registration No.	D1470400012
Valid until:	2027-02-22	Evaluation Report No.	P22-01203-243425

Stuttgart, 2023-04-06

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product:
Anchors Abutments

Intended purpose:
The components are intended for use in prosthetic restorations on dental implants to support procedures in the dental clinic or laboratory

Risk class: IIb

Product:
Anchors

Risk class: IIa

Product:
High-performance polymer for dental prosthesis

Risk class: IIa

Product:
Root canal instrument

Risk class: I (reusable)

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the assessment of the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate D1470400009 dated 02.01.2023 with the following changes:
Supplemented by the products: Anchors and Anchors Abutments