EU Quality Management System Certificate

We hereby certify the company

CeramTec Schweiz GmbH
Bodenäckerstrasse 5
8957 Spreitenbach
Switzerland

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-03-14	Registration No.	D1417400005
Valid until	2028-04-19	Report No.	P23-01158-294066

Stuttgart, 2024-03-14

Notified Body

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

EU Authorized Representative:

CeramTec Dentalvertriebs GmbH
Wallbrunnstraße 24
79539 Lörrach
Germany
DE-AR-000020220

Devices:

Dental Implant System

Intended purpose:
The Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore chewing function. It can be used for single or multiple unit restorations

Risk class: IIb

Dental Abutments

Intended purpose:
Dental abutments are intended to be connected to the dental implants and provide support for prosthetic devices, such as artificial teeth, in order to restore chewing function. They can be used for single or multiple unit restorations

Risk class: IIb

Healing caps

Intended purpose:
The healing caps are intended to seal off the implant during the healing phase

Risk class: IIb

Dental Implants

Intended purpose:
The dental implants are intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore chewing function. They can be used for single or multiple unit restorations

Risk class: IIb

Dental screws

Intended purpose:
Dental screws are intended to fasten the abutments to the implants

Risk class: IIb

Healing abutments

Intended purpose:
Healing abutments are intended to shape the gingiva to fit around prosthetic devices

Risk class: IIb

Reprocessible surgical instruments and tools

Risk class: IIa

Notes:

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

D1417400003 dated 2023-08-15 with the following changes:
Change of company name and legal form from Dentalpoint AG to CeramTec Schweiz GmbH