

EU Quality Management System Certificate

We hereby certify the company

Whitepeaks Dental Solutions GmbH
Weikenrott 17
46499 Hamminkeln
Germany

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 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2024-06-11
Valid until 2027-10-20

Registration No. D1397500035
Report No. P24-00515-302910

Stuttgart, 2024-06-11



Notified Body



Devices:

Blanks for dental technology made of zirconium dioxide, titanium, cobalt chrome, PMMA, PA and PEEK

Risk class: IIa

Colouring liquids for staining of zirconium dioxide ceramics

Risk class: IIa

The certificate is based on the previous certificate

D1397500030 (2022-10-21)

D1397500034 (2024-01-17)

with the following change to D1397500034:

Supplemented by the product: Blanks for dental technology made of zirconium dioxide, titanium, cobalt chrome, PA and PEEK