

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: AT-MF-000004222)

GAMMA medizinisch wissenschaftliche FortbildungsGmbH

Wasserzeile 35
3400 Klosterneuburg
Austria

has implemented and applies a quality management system in accordance with Annex IX, Chapter I 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:	2022-07-19	Registration No.	D4003500008
Valid until:	2027-07-18	Evaluation Report No.	220279

Stuttgart, 2022-07-19



Head of Notified Body



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

Devices:

Product: Gamma Dental Software

Risk class: IIa - not implantable

Product: Dental Motion Analysis System – CADIAX

Risk class: I (measuring function)

Notes:

For class I devices with a measuring function the involvement of mdc is limited to the assessment of the aspects relating to the conformity of the devices with the metrological requirements.