

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: DE-MF-000006308)

LEWA-DENTAL Feinmechanik GmbH & Co. KG

Darmsbacher Straße 3 75196 Remchingen Germany

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:
 2023-09-26
 Registration No.
 D1037500005

 Valid until:
 2028-09-25
 Evaluation Report No.
 P22-01742-253040

Stuttgart, 2023-09-26

Head of Notified Body





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Product: jaw expansion screws, jaw expansion screws for palatal expansion, dental wires, face bows

Risk class: IIa