

EU Quality Assurance Certificate

mdc medical device certification GmbH

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

hereby certifies that the company (SRN: DE-MF-000009288)

MK1 Dental-Attachment GmbH

Am Geeschendamm 2 b 26345 Bockhorn Germany

has implemented and applies a quality management system in accordance with Annex XI, Part A, Section 6 of Regulation (EU) 2017/745 for manufacturing and final inspection of the devices listed on the following pages.

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

Annex XI - Part A (Production Quality Assurance)

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 XI, Section 7 of Regulation (EU) 2017/745.

The 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: Valid until:

2023-09-28 2028-09-27

2023-09-28

Registration No. Evaluation Report No. D1073500015 P22-01748-253159

Stuttgart,

Head of Notified Body





Devices:

Product: retaining elements for removable dental prostheses of lock base made of steel or titanium

Risk class: IIa

EU Quality Assurance Certificate - Registration No. D1073500015