

## 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-000022666)

## DETAX GmbH

Carl-Zeiss-Straße 4 76275 Ettlingen 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 9 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: 2023-08-01 2028-07-31

Registration No. Evaluation Report No. D1002700057 P23-00305-260616

Stuttgart,

2023-08-01

Head of Notified Body

