

EU Quality Management System Certificate

We hereby certify the company

Alleima Dettingen GmbH
Paul-Lechler-Straße 14
72581 Dettingen
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.

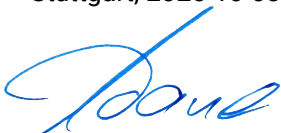
Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

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 2025-10-08
Valid until 2028-05-04

Registration No. D1201100011
Report No. P24-01724-344294

Stuttgart, 2025-10-08



Notified Body



Devices:

stone extraction baskets

Risk class: IIa

guidewires

Risk class: IIa

Polypectomy snares

Intended purpose: Polypectomy snares are used for endoscopic electrosurgical or mechanical removal of polyps and adenomas in the gastrointestinal tract.

Risk class: IIb

The certificate is based on the previous certificate

D1201100008 (2023-05-05)

D1201100009 (2023-07-21)

with the following changes to D1201100009:

Renaming