

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 according to EN ISO 13485

in the scope

development, production and distribution of guidewires, polypectomy snares and stone extractors
as well as precursors for endoscopic instruments and for catheters

An audit by mdc has proven that this quality management system meets the requirements of the following
standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-10-08
Valid until 2026-05-04

Registration No. D1201100010
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Stuttgart, 2025-10-08


Certification Body