

Certificate

We hereby certify the company

Alleima Karlsruhe GmbH
Wilhelm-Schickard-Straße 9c
76131 Karlsruhe
Germany



with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Contract Developer and Contract Manufacturer of surgical instruments, single use instruments,
non-active implants for soft tissue and metal components for medical devices

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 2025-08-21
Valid until 2028-03-15

Registration No. D1084600020
Report No. P25-00059-328392

Stuttgart, 2025-08-21


Certification Body

Sites included in the certification:

Location	Scope
Alleima Karlsruhe GmbH Wilhelm-Schickard-Straße 9c, 76131 Karlsruhe Germany	Contract Developer and Contract Manufacturer of surgical instruments, single use instruments, non-active implants for soft tissue and metal components for medical devices
Alleima Karlsruhe GmbH Lorenzstraße 6, 76297 Stutensee Germany	Contract Developer and Contract Manufacturer of surgical instruments, single use instruments, non-active implants for soft tissue and metal components for medical devices

Stuttgart, 2025-08-21



Certification Body