

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

development and production of medical devices made of shape memory alloys as well as surgical instruments made of titanium and metal alloys, a combination of titanium and metal alloys and shape memory alloys in cleanroom environment

production of implants on behalf of customer specifications in clean room environment

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 2024-05-10
Valid until 2025-03-15

Registration No. D1084600018
Report No. P23-00600-301295

Stuttgart, 2024-05-10



Certification Body



Sites included in the certification:

Location	Scope
Alleima Karlsruhe GmbH Wilhelm-Schickard-Straße 9c 76131 Karlsruhe Germany	development and production of medical devices made of shape memory alloys as well as surgical instruments made of titanium and metal alloys, a combination of titanium and metal alloys and shape memory alloys in cleanroom environment
Alleima Karlsruhe GmbH Lorenzstraße 6 76297 Stutensee Germany	

Stuttgart, 2024-05-10


Certification Body