

For electronic distribution only Nur zur elektronischen Verbreitung

Certificate

We hereby certify the company

ACMIT Gmbh Viktor Kaplan-Straße 2 2700 Wiener Neustadt Austria



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

Quality management system according to EN ISO 13485

in the scope

Design and development services and production of prototypes of general non-implantable active and non-active medical devices, as well as contract manufacturing of medical devices in small batches (optical systems, sensor systems, robotic systems, test and training systems)

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 2025-03-01 Valid until 2028-02-28
 Registration No.
 D4006100004

 Report No.
 P24-01687-320172

Berlin, 2025-02-17

Certification Body



Sites included in the certification:

Location	Scope
ACMIT Gmbh Viktor Kaplan-Straße 2 2700 Wiener Neustadt Austria	Design and development services and production of prototypes of general non-implantable active and non-active medical devices
ACMIT Manufacturing GmbH Viktor Kaplan-Straße 2 2700 Wiener Neustadt Austria	Contract manufacturing of medical devices in small batches (optical systems, sensor systems, robotic systems, test and training systems)

Berlin, 2025-02-17

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Certification Body