Certificate

ECM – Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Talbotstraße 21, 52068 Aachen, Germany

hereby declares that an examination according to DIN EN ISO/IEC 17021-1:2015 of the undermentioned quality assurance system has been carried out.

Through an audit performed on behalf of

medimex GmbH

In den Fritzenstücker 9-11, 65549 Limburg, GERMANY

it could be demonstrated that a quality management system according to

ISO 13485:2016 EN ISO 13485:2016 + AC:2018 + A11:2021 DIN EN ISO 13485:2021

"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the scope:

wholesale of medical devices

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report for the audit mentioned below.

Any substantial changes of the quality management system have to be notified to ecm and are subject to a separate assessment.

Audit-No. 0649-24-1111



Valid until 15 December 2027

Valid as of: 16 December 2024





