

Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.



Through an audit performed on behalf of

MeKo Manufacturing e.K.

Im Kirchenfelde 12-14, 31157 Sarstedt / Hannover, Germany

it could be demonstrated that a quality management system

according to

DIN EN ISO 13485:2016

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

for the

**processing of metals for medical devices
by use of laser processing, heat treatment,
polishing and surface passivation**

has been established and implemented.

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

Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report number

097-21-830

Registered under

Z/22/04780E

Valid until

14 February 2025

Valid as of: 15 February 2022


Certification body