

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

Medizintechnik Sattler GmbH

Werkstr. 9, 07426 Königsee/Thüringen, 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

manufacture, subcontracting, repair and distribution of surgical instruments and accessories and distribution of implants

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

403-21-105

Registered under

Z/21/04763E

Valid until

November 21st, 2024

Valid as of: November 22nd, 2021

A handwritten signature in blue ink, appearing to read 'P. Uef', is written over a horizontal line.

Certification Body