

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

Meditec Source GmbH & Co. KG

Sattlerstraße 19, 78532 Tuttlingen-Nendingen, 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

design, manufacturing and distribution of surgical instruments

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

508-22-0118

Registered under

Z/22/04812E

Valid until

31 March 2025

Valid as of: 01 April 2022

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

Certification body