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

Mecora Medizintechnik GmbH
Rottstrasse 35, 52068 Aachen, 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 of single-use devices packed in sterile packaging**

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	Registered under	Valid until
013-21-1216	**Z/22/04784E**	**07 March 2025**

Valid as of: 08 March 2022

Certification body

ID no. 0045