Certificate

Quality Assurance

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2012.

Through an audit performed on behalf of

medfein Entwicklungs- und Handels GmbH
Dieselstr. 20 a; D-61239 Ober-Mörlen, Germany

it could be demonstrated that a quality assurance system

according to **DIN EN ISO 13485:2012**
"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **development, manufacture and distribution of medical devices**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. 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
173-15-121	Z/15/03526E	21.02.2018

Aachen, February 22nd, 2015

Certification Body