

Certificate

Quality Management System

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

medical2market B.V.

Dr. Stolteweg 70, 8025 AZ Zwolle,, The Netherlands

it could be demonstrated that a quality management system

according to

DIN EN ISO 13485:2012

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

for the

design, manufacturing and distribution of medical devices for the perioperative field

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

489-16-316

Registered under

Z/16/03793E

Valid until

July 9th, 2017

Aachen, April 25th, 2016


Certification Body