

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

intra special catheters GmbH

Oststrasse 2, 66780 Rehlingen-Siersburg, 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, manufacturing 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

218-15-1028

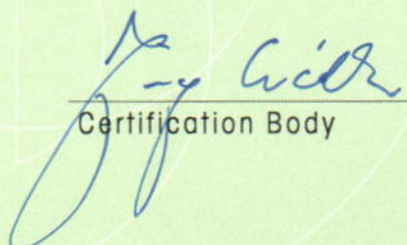
Registered under

Z/15/03697E

Valid until

November 17th, 2018

Aachen, November 18th. 2015



Certification Body