

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

AMEFA GmbH

In den Fritzenstücker 9 - 11, 65549 Limburg, Germany

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

Wholesale 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

648-15-1111

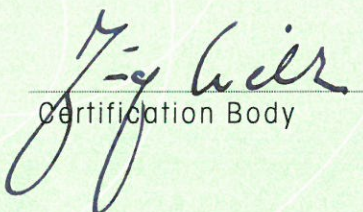
Registered under

Z/15/03715E

Valid until

December 20th, 2018

Aachen, December 21st, 2015


Certification Body