

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

Amedrix GmbH

Schelztorstr, 54-56, 73728 Esslingen, 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 testing of biological implants

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

628-14-56

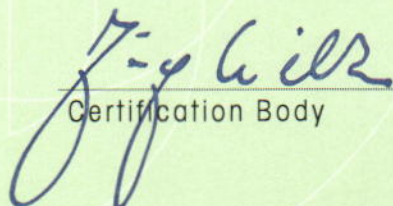
Registered under

Z/14/03363

Valid until

June 30th, 2019

Aachen, July 1st, 2014


Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-052.05.01-46