

Certificate

Quality Assurance

ecm, Bismarckstr. 106, 52066 Aachen hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2010.



Through an audit performed on behalf of

PSM Medical Solutions

Durchhauser Str. 8, 78594 Gunningen, Germany

it could be demonstrated that a quality assurance system

according **DIN EN ISO 13485:2010**
to "Medical devices – Quality management systems – Requirements for regulatory purposes"

for the **design, manufacturing and marketing of surgical instruments, non-active implants, sterile Single-use and reusable medical devices, sterilization boxes and accessories**

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.

Date of initial certification: July 12th, 2004

Date of prolongation: July 13th, 2011

Report Number	Registered under	Valid until
185-11-68	Z/11/02520	July 13 th , 2016

Aachen, July 11th, 2011


Certification Body



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