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

HVM Medical Products GmbH
Industriestraße 11, D-36199 Rotenburg an der Fulda, Germany

it could be demonstrated that a quality assurance system

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

for the **manufacture and distribution of medical devices (sets for infusion, urology and biopsy, filter-sets, hot-cold-systems)**

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	Registered under	Valid until
484-11-69	Z/11/02603	October 21st, 2016

Aachen, October 21st, 2011

Certification Body

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