

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

Impromediform GmbH

Gielster Stück 11, 58513 Lüdenscheid, 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, development and distribution of medical disposables for administration-sets and infusion-sets**

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
179-11-22	Z/11/02562	August 31 st , 2016

Aachen, August 31st, 2011


Certification Body



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