

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

Impromediform GmbH

Gielster Stück 11, 58513 Lüdenscheid, 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

development, manufacturing 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

179-16-32

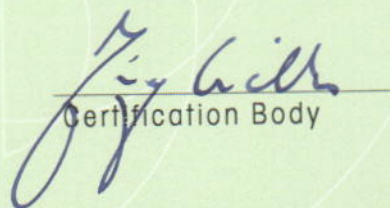
Registered under

Z/16/03932E

Valid until

March 31st, 2019

Aachen, September 30th, 2016


Certification Body