

Certificate

Quality Management System

ecm Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH, Bismarckstr. 106, 52066 Aachen, Germany, hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of DIN EN ISO 13485:2016.



Through an audit performed on behalf of

ASSAmed GmbH

Münchwieser Str. 4, 66450 Bexbach, Germany

it could be demonstrated that a quality management system

according to

DIN EN ISO 13485:2016

"Medical devices – Quality management systems – Requirements for regulatory purposes"

for the

manufacture and distribution of single-use medical devices

has been established and implemented.

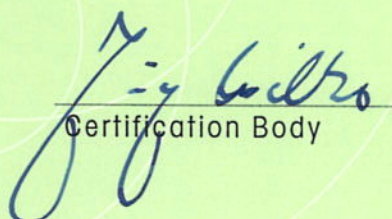
This certificate is only valid under the conditions stated in the audit report mentioned hereafter. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number
053-18-321

Registered under
Z/18/04215E

Valid until
April 12th, 2021

Valid as of: April 13th, 2018


Certification Body