

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

TRIGOCare International GmbH
In den Wiesen 3, 51674 Wiehl, 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

design, manufacture and distribution of medical devices for active woundcare and plaster products

has been established and implemented.

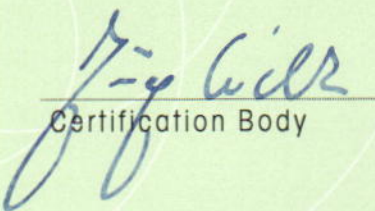
This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number
539-16-21

Registered under
Z/16/03881E

Valid until
August 23rd, 2019

Aachen, August 24th, 2016


Certification Body