

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

Ecomedis medizintechnik gmbh
Gustav-Stresemann-Weg 60, 48155 Münster, 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"

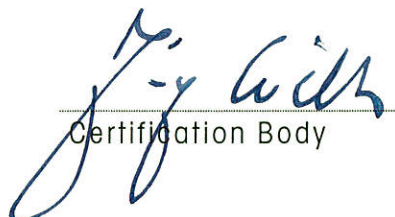
for the **development, manufacturing and sale of single use medical devices**

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.

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|---------------|------------------|------------------------------|
| Report Number | Registered under | Valid until |
| 042-18-423 | Z/18/04256E | June 26 th , 2021 |

Valid as of: June 27th, 2018


Certification Body