

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

preOx RS GmbH

Obertiefenbacher Straße 16, 65614 Beselich, 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

production and distribution of single use medical devices, in-vitro-diagnostics, absorbents, catheters, probes, application and procedure trays for surgery, anaesthesia, gastroenterology and pharmaceutical industry

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

137-19-59

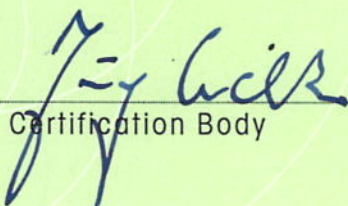
Registered under

Z/19/04576E

Valid until

July 13th, 2022

Valid as of: July 14th, 2019


Certification Body