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-diagnostica, 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	Registered under	Valid until
137-19-59	**Z/19/04576E**	**July 13th, 2022**

Valid as of: July 14th, 2019

Certification Body