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

MEDINORM Medizintechnik GmbH
Gewerbepark 7-9, 66583 Spiesen Elversberg, 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 of drainage system, suction devices, probes, catheters, autotransfusion units and whole blood recovery**

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
147-22-119	**Z/22/04819E**	**31 March 2025**

Valid as of: 01 April 2022

Certification body

ID no. 0045