Certificate

ECM – Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH,
Talbotstraße 21, 52068 Aachen, Germany

hereby declares that an examination according to DIN EN ISO/IEC 17021-1:2015 of the undermentioned quality assurance system has been carried out.

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

ISO 13485:2016
EN ISO 13485:2016 + AC:2018 + A11:2021
DIN EN ISO 13485:2021
„Medical devices – Quality management systems – Requirements for regulatory purposes"

for the scope:
Manufacture, production and distribution of:
Sterile surgical suction, sterile wound drainage systems, sterile pleural puncture sets, sterile products for airway and oxygen supply, sterile urological and proctological catheters, sterile probes, sterile transfer cannulas and sterile assistant trays with spatulas.
As well as production of sterile applicators and non-sterile medical tubes and tube systems.

has been established and implemented.

This certificate is only valid under the conditions stated in the audit report for the audit mentioned below.

Any substantial changes of the quality management system have to be notified to ecm and are subject to a separate assessment.

Audit-No.	Registered under	Valid until
0147-25-0219	Z/25/04877E	30 March 2028

Valid as of: 31 March 2025

Certification body

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

DAkkS Deutsche Akkreditierungsstelle D-ZM-21753-01-00

ID 0374