

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.

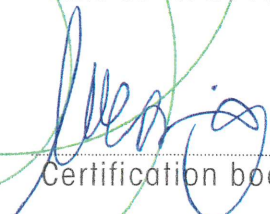
Any substantial changes of the quality management system have to be
notified to ecm and are subject to a separate assessment.

Audit-No.
0147-26-0409

Registered under
Z/26/04905E

Valid until
30 March 2028

Valid as of: 28 April 2026


Certification body

