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

VYGON Germany GmbH
Prager Ring 100,
52070 Aachen, GERMANY

previous company name:
Vygon GmbH & Co. KG
Prager Ring 100, 52074 Aachen, 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:

Design and development, manufacture and distribution of catheters and catheter sets for peripheral, central, venous, arterial, short and long-term applications, accessories for catheter insertion and accessories for intravenous infusion management.
Distribution of catheters and medical devices for infusion management

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
0948-25-0114	**Z/25/04889E**	**9 February 2028**

Valid as of: 12 June 2025

Certification body

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

ID 0374