By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

VYGON Germany GmbH
Prager Ring 100
Aachen
52070
Germany

Holds Certificate Number: MD 848733

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and development, manufacture and distribution of catheters and catheter sets for peripheral, central, venous, arterial, otological, short and long-term applications, accessories for catheter insertion and accessories for intravenous infusion management.
Distribution of catheters and medical devices for infusion management.
Transfer from: ECM - Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH
Certificate reference: Z/26/04907E

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-11-09
Effective Date: 2026-11-09
Latest Revision Date: 2026-11-09
Expiry Date: 2028-02-09

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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