

Certificate of Registration

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

This is to certify that:

Mermaid Medical A/S
Frydensbergvej 25
Stenløse
3660
Denmark

Holds Certificate Number:

MD 801435

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

Design, manufacture and distribution of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-03-07

Latest Revision Date: 2026-09-04

Effective Date: 2026-09-16

Expiry Date: 2029-09-15

Page: 1 of 2



...making excellence a habit.™

Certificate No: MD 801435

Location	Registered Activities
Mermaid Medical A/S Frydensbergvej 25 Stenløse 3660 Denmark	Manufacture of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S 8033 Cooper Creek Blvd Suite 106 University Park Florida 34201 USA	Design of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S Knud Bro Alle 5b-d Stenløse 3660 Denmark	Distribution of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S Knud Bro Alle 4 Stenløse 3660 Denmark	Distribution of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S Knud Bro Alle 8 Stenløse 3660 Denmark	Distribution of biopsy and coaxial needles, catheters, inferior vena cava filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.

Original Registration Date: 2024-03-07

Latest Revision Date: 2026-09-04

Effective Date: 2026-09-16

Expiry Date: 2029-09-15

Page: 2 of 2

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

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.