

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Mermaid Medical A/S
Frydensbergvej 25
Stenløse
3660
Denmark

Facility ID Number: F007166

Holds Certificate No:

MDSAP 801433

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Manufacture, and Distribution of biopsy and coaxial needles, catheters, inferior vena cava (IVC) 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: 2024-04-17

Effective Date: 2026-09-16

Expiry Date: 2029-09-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 801433**

Location	Registered Activities
Mermaid Medical A/S Frydensbergvej 25 Stenløse 3660 Denmark Facility ID Number: F007166	Manufacture of biopsy and coaxial needles, catheters, IVC 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 Facility ID Number: F007166	Distribution of biopsy and coaxial needles, catheters, IVC filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S Knud Bro Alle 4 Stenløse 3660 Denmark Facility ID Number: F007166	Distribution of biopsy and coaxial needles, catheters, IVC filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.
Mermaid Medical A/S Knud Bro Alle 8 Stenløse 3660 Denmark Facility ID Number: F007166	Distribution of biopsy and coaxial needles, catheters, IVC 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 Facility ID Number: F007194	Design of biopsy and coaxial needles, catheters, IVC filters with catheters, guidewires, percutaneous introducer sets for the area of general surgery.

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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

A Member of the BSI Group of Companies.