

# 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 and manufacture of aspiration and access needles, biopsy needles and instruments, mechanical thrombectomy systems, catheters, centesis catheters, drainage catheters, 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: 2025-06-09

Expiry Date: 2026-09-15



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	QA, administration, production.
Mermaid Medical A/S Knud Bro Alle 5b-d Stenløse 3660 Denmark Facility ID Number: F007166	Customer service, purchasing, warehouse.
Mermaid Medical A/S Knud Bro Alle 4 Stenløse 3660 Denmark Facility ID Number: F007166	Finance, warehouse.
Mermaid Medical A/S Knud Bro Alle 8 Stenløse 3660 Denmark Facility ID Number: F007166	Sales & Marketing.
Mermaid Medical A/S 8033 Cooper Creek Blvd Suite 106 University Park Florida 34201 USA Facility ID Number: F007194	R&D, RA

Original Registration Date: 2024-04-17      Effective Date: 2025-06-09      Expiry Date: 2026-09-15

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](#)  
To be read in conjunction with the scope above or the attached appendix.