

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:


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

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, guidewires, percutaneous introducer sets for the area of general surgery.

Transfer from UL Solutions
Certificate Number: 2390.230916

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-04-17

Effective Date: 2024-04-17

Expiry Date: 2026-09-15



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 2

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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: 2024-04-17 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.