

CERTIFICATE OF REGISTRATION

Mermaid Medical A/S

Frydensbergvej 25
DK-3660 Stenløse DENMARK

Facility ID: F002649

UL Medical Regulatory Services of UL LLC® (UL Solutions) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

EN ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

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.

With additional locations listed on Addendum: 1



Authorized by



Paul Hilgeman
Senior Business Manager - Medical
CMIT – Medical Regulatory



Check Certificate Status:
[here](#)

File Number	A28721	Cycle Start Date	September 16, 2023
Certificate Number	2390.230916	Effective Date	September 16, 2023
Initial Issue Date	January 24, 2019	Expiry Date	September 15, 2026

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC® (UL Solutions). Certificates may be verified by visiting the Online Certifications Directory on UL.com.



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Services UL, LLC is an
MDSAP Recognized
Auditing Organization**

UL Solutions
333 Pfingsten Road
Northbrook, IL 60062-2096 USA



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Addendum 1

1-1 Mermaid Medical A/S
Facility ID: F002649 Frydensbergvej 25
DK-3660 Stenloese DENMARK
Performing: QA, administration, production.

1-2 Mermaid Medical A/S
Facility ID: F002649 Knud Bro Alle 5b-d
DK-3660 Stenloese DENMARK
Performing: Customer service, purchasing, warehouse.

1-3 Mermaid Medical A/S
Facility ID: F002649 Knud Bro Alle 4
DK-3660 Stenloese DENMARK
Performing: Finance, warehouse.

1-4 Mermaid Medical A/S
Facility ID: F002649 Knud Bro Alle 8
DK-3660 Stenloese DENMARK
Performing: Sales & Marketing

2-1 Mermaid Medical A/S
Facility ID: F006719 8033 Cooper Creek Blvd., Unit 106 University Park
FL 34201 Sarasota UNITED STATES
Performing: R&D, RA

Table with registration details: File Number, Certificate Number, Initial Issue Date, Cycle Start Date, Effective Date, Expiry Date.

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Solutions

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Additional Regulatory Requirements

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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