CERTIFICATE OF REGISTRATION

Mermaid Medical A/S

Frydensbergvej 25
DK-3660 Stenloese
DENMARK

REPs Facility ID: F002649

UL Medical Regulatory Services of UL LLC®(UL) 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

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Deborah Jennings-Conner
Global Regulatory Director
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A28721	Cycle Start Date	September 16, 2020
Certificate Number	2390.210628	Effective Date	June 28, 2021
Initial Issue Date	January 24, 2019	Expiry Date	September 15, 2022

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.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

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

CERTIFICATE OF REGISTRATION

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Addendum 1

1-2	**Mermaid Medical A/S**
REPs Facility ID: **F002649**	**Knud Bro Alle 5b-d**
	Stenloese DK-3660 DENMARK

Performing: Customer service, purchasing, warehouse.

1-3	**Mermaid Medical A/S**
REPs Facility ID: **F002649**	**Knud Bro Alle 4**
	Stenloese DK-3660 DENMARK

Performing: Sales and marketing, warehouse.

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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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