

Quality System Certificate

Certificate No.:
DGM – 769

Reference:
auriso2004v250f759

Date of issue:
2020-09-22

Valid Until:
2023-10-23

Initial date of issue:
2011-11-03

This is to certify that the quality system of:

Mermaid Medical A/S
Frydensbergvei 25
3660 Stenløse
Denmark

fulfills the requirements in:

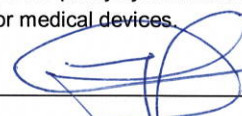
DS/EN ISO 13485:2016

The certificate covers the following activities:

Design, manufacture, sales and distribution of soft tissue biopsy needles, access needle for guidewire and drainage catheters.
Sales and distribution of medical devices.

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

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Additional site(s) covered by the certificate:

Mermaid Medical A/S
Knud Bro Allé 5B-5D
3660 Stenløse
Denmark

Mermaid Medical A/S
Knud Bro Allé 4
3660 Stenløse
Denmark