

Quality System Certificate

Certificate No.:
DGM – 769

Reference:
Aur2a1812v190f759

Date of issue:
2019-01-04

Valid Until:
2020-10-23

Initial date of issue:
2011-11-03

This is to certify that the quality system of:

Mermaid Medical A/S
Frydensbergvej 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