



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding section 4

Certificate No.:
DGM – 768

Reference:
Aur2a1812v190f759

Date of issue:
2019-01-04

Valid Until:
2019-10-23

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

has been audited under the requirements of:

Annex II, Full quality assurance system, excluding section 4, of Council Directive 93/42/EEC as transposed into Danish law. The quality system meets the requirements of the MDD, Annex II. For the placing on the market of class III products covered by this certificate an Annex II section 4 certificate is required.

The certificate covers the following activities:

Design and manufacture of soft tissue biopsy needle and access needle for guidewire and drainage catheters in class IIb and IIa

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. This EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the MDD, Annex II, section 5.

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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The following product(s)/product families in class IIb are covered by the certificate:

Product family

M-Drain Drainage Catheters

GMDN code

47796; 10696

The following product(s)/product families in class IIa are covered by the certificate:

Product family

Trocar, Spinal and PTFE needles

M-Drain Drainage Catheters

M-Drain Percutaneous Introducer System

M-Drain Centesis Catheter

Fine Needle Aspiration

M-Biopsy Biopsy Needles for Reusable Biopsy Instruments

M-Biopsy SemiAutomatic Instrument and Coaxial Introducer Needles

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