

This is to certify that the quality system of:

Vigmed AB
Garnisonsgatan 10
254 66 Helsingborg
Sweden

has been approved in conformity with the requirements of:

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design and manufacture of hypodermic needle with safety cover, I.V Catheter and arterial catheter in class IIa and safety covers in class Is

This EC certificate is issued in accordance with Presafe Denmark A/S' 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 Directive.



Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

Date of issue: 2015-11-04
Expires: 2019-07-09
Initial date of issue: 2014-11-13
Reference: aur2a1503v42f810

The following products in class IIa are covered by the certificate:

SWING Universal with needles

SWITCH Needle-protected Safety Catheter

CLIP Safety I.V. Catheter

The following products in class Is are covered by the certificate:

SWiNG Universal without needles

Certificate number: DGM – 848
Certificate type: EC Certificate

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