

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000374687-PA-NA-DNK Rev 0.0

Project No.:
PRJN-189901-2020-PA-DNK

Valid Until:
26 May 2024

This is to certify that the quality system of:

Vigmed AB

Kungsgatan 6
252 21 Helsingborg
Sweden

For design, production and final product inspection/testing of:
**DESIGN AND MANUFACTURE OF HYPODERMIC NEEDLE
WITH SAFETY COVER, I.V CATHETER, ARTERIAL CATHETER
AND SAFETY COVERS.**

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE
93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 25 June 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM -848 to DNV GL Presafe A/S (NB2460)	25 June 2020

Products covered by this Certificate:

Product Description	Product Name	Class
SWiNG Universal without needles	<ul style="list-style-type: none"> SWiNG Universal without needles 	Is
SWiNG Universal with needles	<ul style="list-style-type: none"> SWiNG Universal with needles 	IIa
SWITCH Needle-protected Safety Catheter	<ul style="list-style-type: none"> SWITCH (SW 20 45 01, SW 22 45 01, SW 22 35 01, SW 20 45 11, SW 22 45 11, SW 22 35 11) 	IIa
CLiP Safety I.V. Catheter	<ul style="list-style-type: none"> CLiP® Ported (VP 14 45 01, VP 16 45 01, VP 17 45 01, VP 18 45 01, VP 18 32 01, VP 20 32 01, VP 20 25 01, VP 22 25 01, VP 14 45 11, VP 16 45 11, VP 17 45 11, VP 18 45 11, VP 18 32 11, VP 20 32 11, VP 20 25 11, VP 22 25 11, VP 24 19 01, VP 24 19 11) 	IIa
	<ul style="list-style-type: none"> CLiP® Winged (VW 14 45 01, VW 16 45 01, VW 17 45 01, VW 18 45 01, VW 18 32 01, VW 20 32 01, VW 22 25 01, VW 14 45 11, VW 16 45 11, VW 17 45 11, VW 18 45 11, VW 18 32 11, VW 20 32 11, VW 22 25 11, VW 24 19 11) 	
	<ul style="list-style-type: none"> CLiP® Neo (NW 24 19 01, NW 26 19 01) 	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Vigmed AB	Kungsgatan 6, 252 21 Helsingborg Sweden

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Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate