
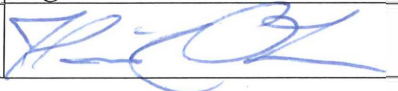


This report is issued by:

<i>Role</i>	<i>Date</i>	<i>Signature</i>
Åsa Westrup QA/RA Manager	2022-03-14	

This report is approved by:

<i>Role</i>	<i>Date</i>	<i>Signature</i>
Henrik Olsen CEO	2022-03-14	

Appendix

<i>Identity</i>	<i>Title</i>
Appendix 1	Declaration of conformity (DoC) CLiP

References

<i>Identity</i>	<i>Title</i>
-	-

Change History

<i>Version</i>	<i>Date</i>	<i>Ref.</i>	<i>Change History</i>
1	2019-01-21	CRF0098	Implementation of new product Id no VP202501 and VP202511 DoC receives document number Earlier versions did not include document number or version traceability (except for title and date)
2	2019-02-21	CRF0092a	Rebrandat DoC to GBO layout
3	2019-06-07	-	Removal of product ID ending with 02 and 12, that has never been used. Reason: Presafe comment at renewal of EC certificate.
4	2019-07-02	CC-2018-08	Addition of new product VW241911
5	2019-07-31	-	Issued new DoC after receiving new EC certificate Change of title in column heads to: Product group, Product description and Product code from earlier Product name (Ported/Winged/Neo) and Product ID
6	2020-06-24	CC-2020-02a CC-2020-03a	Notify body number changed from Presafe Denmark A/S Identification No 0543 to DNV GL Presafe AS Identification No 2460. EC certificate No DGM-848 changed to 10000374687-PA-NA-DNK Rev 0.0 Legal manufacturing address changed from Garnisonsgatan 10, 254 66 Helsingborg to Kungsgatan 6, 252 21 Helsingborg. Business address changed to Address
7	2021-04-30	CC-2021-05	GMDN number changed to 64574 due to the old number being obsolete
8	2022-03-14	DNV TF review NC1	DNV GL Presafe AS changed name to DNV Product Assurance AS. Appendix 1 updated accordingly.

1 SCOPE

This word file is only to be able to track change history for Appendix 1. Formal approval is done in Appendix 1.

DECLARATION OF CONFORMITY

Manufacturer's name: Vigmed AB

Address: Kungsgatan 6,
SE-252 21 Helsingborg,
SWEDEN

Product group(s): CLiP® (Ported, Winged, Neo)

Product description: Automatic safety I.V. catheter

Classification: Class IIa

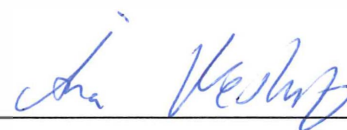
Assessment route: Annex II, MDD 93/42/EEC

Notified body: DNV Product Assurance AS Identification No. 2460
Vigmed EC certificate No 10000374687-PA-NA-DNK Rev 0.0

GMDN: 64574

Vigmed hereby declares that the product group above, fulfils applicable requirements of the Swedish Medical Device Act SFS 1993:584 and Swedish Regulation LVFS 2003:11, enforcing the European Medical Device Directive 93 / 42 / EEC.

PRODUCT GROUP	PRODUCT DESCRIPTION	PRODUCT CODE
CLiP® Ported	Automatic safety I.V. catheter	VP144511
CLiP® Ported	Automatic safety I.V. catheter	VP164511
CLiP® Ported	Automatic safety I.V. catheter	VP174511
CLiP® Ported	Automatic safety I.V. catheter	VP184511
CLiP® Ported	Automatic safety I.V. catheter	VP183211
CLiP® Ported	Automatic safety I.V. catheter	VP203211
CLiP® Ported	Automatic safety I.V. catheter	VP202511
CLiP® Ported	Automatic safety I.V. catheter	VP222511
CLiP® Ported	Automatic safety I.V. catheter	VP241911
CLiP® Ported	Automatic safety I.V. catheter	VP144501
CLiP® Ported	Automatic safety I.V. catheter	VP164501
CLiP® Ported	Automatic safety I.V. catheter	VP174501
CLiP® Ported	Automatic safety I.V. catheter	VP184501
CLiP® Ported	Automatic safety I.V. catheter	VP183201
CLiP® Ported	Automatic safety I.V. catheter	VP203201
CLiP® Ported	Automatic safety I.V. catheter	VP202501
CLiP® Ported	Automatic safety I.V. catheter	VP222501
CLiP® Ported	Automatic safety I.V. catheter	VP241901
CLiP® Winged	Automatic safety I.V. catheter	VW144511
CLiP® Winged	Automatic safety I.V. catheter	VW164511
CLiP® Winged	Automatic safety I.V. catheter	VW174511
CLiP® Winged	Automatic safety I.V. catheter	VW184511
CLiP® Winged	Automatic safety I.V. catheter	VW183211
CLiP® Winged	Automatic safety I.V. catheter	VW203211
CLiP® Winged	Automatic safety I.V. catheter	VW222511
CLiP® Winged	Automatic safety I.V. catheter	VW241911
CLiP® Winged	Automatic safety I.V. catheter	VW144501
CLiP® Winged	Automatic safety I.V. catheter	VW164501
CLiP® Winged	Automatic safety I.V. catheter	VW174501
CLiP® Winged	Automatic safety I.V. catheter	VW184501
CLiP® Winged	Automatic safety I.V. catheter	VW183201
CLiP® Winged	Automatic safety I.V. catheter	VW203201
CLiP® Winged	Automatic safety I.V. catheter	VW222501
CLiP® Neo	Automatic safety I.V. catheter	NW241901
CLiP® Neo	Automatic safety I.V. catheter	NW261901



Åsa Westrup, QA/RA Manager Vigmed AB
Helsingborg, 2022-03-14