
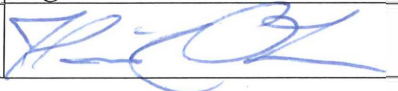


This report is issued by:

| <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

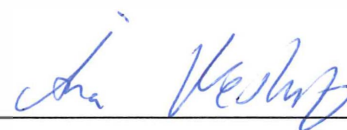
Assessment route: Annex II, MDD 93/42/EEC

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