
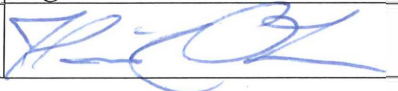


**This report is issued by:**

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

**This report is approved by:**

| <i>Role</i>         | <i>Date</i> | <i>Signature</i>  |
|---------------------|-------------|---|
| Henrik Olsen<br>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<br>DoC receives document number<br>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<br>Change of title in column heads to:<br>Product group, Product description and Product code from earlier<br>Product name (Ported/Winged/Neo) and Product ID   |
| 6              | 2020-06-24  | CC-2020-02a<br><br>CC-2020-03a | Notify body number changed from Presafe Denmark A/S Identification No 0543 to DNV GL Presafe AS Identification No 2460.<br>EC certificate No DGM-848 changed to 10000374687-PA-NA-DNK Rev 0.0<br>Legal manufacturing address changed from Garnisonsgatan 10, 254 66 Helsingborg to Kungsgatan 6, 252 21 Helsingborg.<br>Business address changed to Address |
| 7              | 2021-04-30  | CC-2021-05                     | GMDN number changed to <b>64574</b> due to the old number being obsolete  |
| 8              | 2022-03-14  | DNV TF review<br>NC1           | DNV GL Presafe AS changed name to DNV Product Assurance AS.<br>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

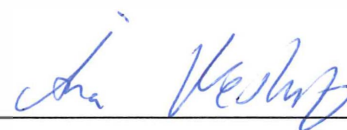
**Assessment route:** Annex II, MDD 93/42/EEC

**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