Report ID **QR0925** Version 5

Title: **Declaration of conformity (DoC) SWiTCH** Date 2022-03-14

This report is issued by:

Role	*Date*	*Signature*
Åsa Westrup QA/RA Manager	2022-03-14	

This report is approved by:

Role	*Date*	*Signature*
Henrik Olsen CEO	2022-03-14	

Appendix

Identity	*Title*
Appendix 1	Declaration of conformity (DoC) SWiTCH

References

Identity	*Title*
-	-

Change History

Version	*Date*	*Ref.*	*Change History*
1	2019-02-21	CRF0092a	Rebrandat DoC to GBO layout DoC receives document number Earlier versions did not include document number or version traceability (except for title and date)
2	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
3	2020-06-24	CC-2020-02b CC-2020-03b	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
4	2021-04-30	CC-2021-05	GMDN number changed to **64575** due to the old number being obsolete.
5	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.

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DECLARATION OF CONFORMITY

Manufacturer's name:	Vigmed AB
Address:	Kungsgatan 6, SE-252 21 Helsingborg, SWEDEN
Product group(s):	SWiTCH
Product description:	Automatic safety arterial 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:	64575

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
SWiTCH	Automatic safety arterial catheter	SW204511
SWiTCH	Automatic safety arterial catheter	SW224511
SWiTCH	Automatic safety arterial catheter	SW223511
SWiTCH	Automatic safety arterial catheter	SW204501
SWiTCH	Automatic safety arterial catheter	SW224501
SWiTCH	Automatic safety arterial catheter	SW223501

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