EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until
10000457530-PA-NA-DNK-Rev 0.0	PRJN-243048-2021-PA-DNK	01 November 2022

This is to certify that :

Hydrophilic coated guide wires

Manufactured by:

SP Medical A/S

Møllevej 1, 4653 Karise, Denmark

Has been assessed with respect to:

examination of the design of the product as described in Annex II 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, 07 May 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Eugenie Winger Husebye
Technical reviewer

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-786 to DNV Product Assurance AS (NB 2460)	07 May 2021

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
Poseidon Hydrophilic Nitinol Guide Wires - Straight tip Hy-N-S-ST-018-D-L, Hy-N-S-ST-025-D-L, Hy-N-S-ST-032-D-L, Hy-N-S-ST-035-D-L, Hy-N-S-ST-038-D-L, Hy-N-S-ST-025-H-L, Hy-N-S-ST-032-H-L, Hy-N-S-ST-035-H-L, Hy-N-S-ST-038-H-L, Hy-N-S-SO-018-D-L, Hy-N-S-SO-025-D-L, Hy-N-S-SO-032-D-L, Hy-N-S-SO-035-D-L, Hy-N-S-SO-038-D-L, Hy-N-S-SO-025-H-L, Hy-N-S-SO-032-H-L, Hy-N-S-SO-035-H-L, Hy-N-S-SO-038-H-L, Hy-N-S-F-018-D-L, Hy-N-S-F-025-D-L, Hy-N-S-F-032-D-L, Hy-N-S-F-035-D-L, Hy-N-S-F-038-D-L, Hy-N-S-F-025-H-L, Hy-N-S-F-032-H-L, Hy-N-S-F-035-H-L, Hy-N-S-F-038-H-L	III	35094 & 58115
Poseidon Hydrophilic Nitinol Guide Wires - Reshapeable tip Hy-N-R-ST-018-D-L, , Hy-N-R-ST-025-D-L, Hy-N-R-ST-032-D-L, Hy-N-R-ST-035-D-L, Hy-N-R-ST-038-D-L, Hy-N-R-ST-025-H-L, Hy-N-R-ST-032-H-L, Hy-N-R-ST-035-H-L, Hy-N-R-ST-038-H-L, Hy-N-R-SO-018-D-L, Hy-N-R-SO-025-D-L, Hy-N-R-SO-032-D-L, Hy-N-R-SO-035-D-L, Hy-N-R-SO-038-D-L, Hy-N-R-SO-025-H-L, Hy-N-R-SO-032-H-L, Hy-N-R-SO-035-H-L, Hy-N-R-SO-038-H-L, Hy-N-R-F-018-D-L, Hy-N-R-F-025-D-L, Hy-N-R-F-032-D-L, Hy-N-R-F-035-D-L, Hy-N-R-F-038-D-L, Hy-N-R-F-025-H-L, Hy-N-R-F-032-H-L, Hy-N-R-F-035-H-L, Hy-N-R-F-038-H-L	III	35094 & 58115
Poseidon Hydrophilic Nitinol Guide Wires - Angled tip Hy-N-A-ST-018-D-L, Hy-N-A-ST-025-D-L, Hy-N-A-ST-032-D-L,	III	35094 & 58115

Hy-N-A-ST-035-D-L, Hy-N-A-ST-038-D-L, Hy-N-A-ST-025-H-L, Hy-N-A-ST-032-H-L, Hy-N-A-ST-035-H-L, Hy-N-A-ST-038-H-L, Hy-N-A-SO-018-D-L, Hy-N-A-SO-025-D-L, Hy-N-A-SO-032-D-L, Hy-N-A-SO-035-D-L, Hy-N-A-SO-038-D-L, Hy-N-A-SO-025-H-L, Hy-N-A-SO-032-H-L, Hy-N-A-SO-035-H-L, Hy-N-A-SO-038-H-L, Hy-N-A-F-018-D-L, Hy-N-A-F-025-D-L, Hy-N-A-F-032-D-L, Hy-N-A-F-035-D-L, Hy-N-A-F-038-D-L, Hy-N-A-F-025-H-L, Hy-N-A-F-032-H-L, Hy-N-A-F-035-H-L, Hy-N-A-F-038-H-L		
Poseidon Hydrophilic Nitinol Guide Wires - Double Ended DE-Hy-N-A-ST-S-SO-035-H-L	III	35094 & 58115
Short description of the Medical Device:		
Hydrophilic coated guide wires		

Description of product identifier codes used for product family **Poseidon Hydrophilic Nitinol Guide Wires**

Hy is Hydrophilic
N is Nitinol Steel
A is angled tip
R is reshapable tip
S is straight
DE is double-ended
F is floppy tip stiffness
SO is soft tip stiffness
ST is standard tip stiffness
018, 025, 032, 035 and **038** is the guide wire diameters in inches.
D is standard shaft stiffness
H is stiff shaft stiffness
L is a variable
L is the total length of the guide wire in the range from 30 cm to 260 cm.

Allowed Optional variants
A suffix **AAYY** can if needed be added at the end of the above listed product identifiers:
Purpose, handle national label requirements and identification of different distributors in specific countries
AA is country abbreviation written with 2 characters.
YY is a number from 01 to 99 in cases were product identifier is to identify specific distributors in specific countries.

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 the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System. 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.

End of Certificate