



DNV

EC Design Examination Certificate

Certificate No.:

10000457518-PA-NA-DNK-Rev 0.0

Project No.:

PRJN-243048-2021-PA-DNK

Valid Until

03 March 2022

This is to certify that :

PTFE and stainless steel Guide Wires

Manufactured by:

SP Medical A/S

Møllevvej 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

For the issuing office:

**Notified Body 2460
DNV Product Assurance AS**



Eugenie Winger Husebye
Eugenie Winger Husebye
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-11-MDD-f4, rev.0

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-780 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:
Accoat Guide Wires - Seldinger Straight S-018-L, S-021-L, S-025-L, S-028-L, S-032-L, S-035-L, S-038-L, S-C-018-L, S-C-021-L, S-C-025-L, S-C-028-L, S-C-032-L, S-C-035-L, S-C-038-L, H-S-018-L, H-S-021-L, H-S-025-L, H-S-028-L, H-S-032-L, H-S-035-L, H-S-038-L, H-S-C-018-L, H-S-C-021-L, H-S-C-025-L, H-S-C-028-L, H-S-C-032-L, H-S-C-035-L, H-S-C-038-L, H-X-S-028-L, H-X-S-032-L, H-X-S-035-L, H-X-S-038-L, H-X-S-C-028-L, H-X-S-C-032-L, H-X-S-C-035-L, H-X-S-C-038-L, H-X-X-S-028-L, H-X-X-S-032-L, H-X-X-S-035-L, H-X-X-S-038-L, H-X-X-S-C-028-L, H-X-X-S-C-032-L, H-X-X-S-C-035-L, H-X-X-S-C-038-L	III	35094 & 58115
Accoat Guide Wires - Seldinger J-tip Jr-018-L, Jr-021-L, Jr-025-L, Jr-028-L, Jr-032-L, Jr-035-L, Jr-038-L, Jr-C-018-L, Jr-C-021-L, Jr-C-025-L, Jr-C-028-L, Jr-C-032-L, Jr-C-035-L, Jr-C-038-L, H-Jr-018-L, H-Jr-021-L, H-Jr-025-L, H-Jr-028-L, H-Jr-032-L, H-Jr-035-L, H-Jr-038-L, H-Jr-C-018-L, H-Jr-C-021-L, H-Jr-C-025-L, H-Jr-C-028-L, H-Jr-C-032-L, H-Jr-C-035-L, H-Jr-C-038-L, H-X-Jr-028-L, H-X-Jr-032-L, H-X-Jr-035-L, H-X-Jr-038-L, H-X-Jr-C-028-L, H-X-Jr-C-032-L, H-X-Jr-C-035-L, H-X-Jr-C-038-L, H-X-X-Jr-028-L, H-X-X-Jr-032-L, H-X-X-Jr-035-L, H-X-X-Jr-038-L, H-X-X-Jr-C-028-L, H-X-X-Jr-C-032-L, H-X-X-Jr-C-035-L,	III	35094 & 58115

H-X-X-Jr-C-038-L		
<p>Accoat Guide Wires - Seldinger Double Ended</p> <p>D-S-Jr-025-L, D-S-Jr-032-L, D-S-Jr-035-L, D-S-Jr-038-L, D-S-Jr-C-025-L, D-S-Jr-C-032-L, D-S-Jr-C-035-L, D-S-Jr-C-038-L, H-D-S-Jr-025-L, H-D-S-Jr-032-L, H-D-S-Jr-035-L, H-D-S-Jr-038-L, H-D-S-Jr-C-025-L, H-D-S-Jr-C-032-L, H-D-S-Jr-C-035-L, H-D-S-Jr-C-038-L</p>	III	35094 & 58115
<p>Accoat Guide Wires - Seldinger Movable</p> <p>M-S-032-L, M-S-035-L, M-S-038-L, M-S-C-032-L, M-S-C-035-L, M-S-C-038-L, M-Jr-032-L, M-Jr-035-L, , M-Jr-038-L, M-Jr-C-032-L, M-Jr-C-035-L, M-Jr-C-038-L, H-M-S-032-L, H-M-S-035-L, H-M-S-038-L, H-M-S-C-032-L, H-M-S-C-035-L, H-M-S-C-038-L, H-M-Jr-032-L, H-M-Jr-035-L, H-M-Jr-038-L, H-M-Jr-C-032-L, H-M-Jr-C-035-L, H-M-Jr-C-038-L</p>	III	35094 & 58115
Short description of the Medical Device:		
PTFE and stainless steel Guide Wires		

Description of product identifier codes used for product family Accoat Guide Wires:	
Description of codes used for Seldinger Straight:	
S (straight) is the shape of the tip	L is a variable
C is PTFE coated	L is the total length of the guide wire in the range from 10 cm to 450 cm.
018-038 is the diameter in inches.	
H is stiff, H-X is extra stiff and H-X-X is super stiff	
Description of codes used for Seldinger J-tip:	
Jr is the shape of the tip in mm (rad. 1,5-15mm)	L and r are variables
C is PTFE coated	L is the total length of the guide wire in the range from 10 cm to 450 cm.
018-038 is the diameter in inches.	r is the radius of the J tip in the range from 1, 5 mm to 15 mm.
H is stiff, H-X is extra stiff and H-X-X is super stiff	
Description of codes used for Seldinger Double Ended:	
D is double ended Guide Wire (one end straight and one end Jr)	L and r are variables
C is PTFE coated	L is the total length of the guide wire in the range from 30 cm. to 450 cm.
025-038 is the diameter in inches.	r is the radius of the J tip in the range from 1, 5 mm. to 15 mm.
H is stiff and H-X is extra stiff	
Description of codes used for Description of codes used for Seldinger Movable:	
M is a movable Guide Wire	L and r are variables in the product identifier
S (straight) is the shape of the tip	L is the total length of the guide wire in the range from 30 cm. to 450 cm.
Jr is the shape of the tip in mm (rad. 1,5-15 mm)	r is the radius of the J tip in the range from 1, 5 mm. to 15 mm.
C is PTFE coated	
032-038 is the diameter in inches.	
H is stiff	
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