

This is to certify that the defined representative samples of the device manufactured by:

SP Medical A/S
Møllevej 1
4653 Karise
Denmark

have been approved in conformity with the requirements of

Annex II Section 4 - Examination of the design of the product

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following devices:

Hydrophilic coated guide wires in class III

The Design Examination certificate is valid provided that no changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices as transposed into Danish law. The certificate is based on successful evaluation of the device design.



Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2018-09-06
Expires: 2022-11-01
Initial date of issue: 2012-07-02
Reference: aur2a1809v260f766

The following products in class III are covered by the certificate:

Poseidon Hydrophilic Nitinol Guide Wires

Straight tip

REF Number	Date for first CE Mark
Hy-N-S-ST-018-D-L	2012.07.02
Hy-N-S-ST-025-D-L	2012.07.02
Hy-N-S-ST-032-D-L	2012.07.02
Hy-N-S-ST-035-D-L	2012.07.02
Hy-N-S-ST-038-D-L	2012.07.02
Hy-N-S-ST-025-H-L	2012.07.02
Hy-N-S-ST-032-H-L	2012.07.02
Hy-N-S-ST-035-H-L	2012.07.02
Hy-N-S-ST-038-H-L	2012.07.02
Hy-N-S-SO-018-D-L	2015.12.08
Hy-N-S-SO-025-D-L	2012.07.02
Hy-N-S-SO-032-D-L	2012.07.02
Hy-N-S-SO-035-D-L	2012.07.02
Hy-N-S-SO-038-D-L	2012.07.02
Hy-N-S-SO-025-H-L	2012.07.02
Hy-N-S-SO-032-H-L	2012.07.02
Hy-N-S-SO-035-H-L	2012.07.02
Hy-N-S-SO-038-H-L	2012.07.02
Hy-N-S-F-018-D-L	2015.12.08
Hy-N-S-F-025-D-L	2012.07.02
Hy-N-S-F-032-D-L	2012.07.02
Hy-N-S-F-035-D-L	2012.07.02
Hy-N-S-F-038-D-L	2012.07.02
Hy-N-S-F-025-H-L	2012.07.02
Hy-N-S-F-032-H-L	2012.07.02
Hy-N-S-F-035-H-L	2012.07.02
Hy-N-S-F-038-H-L	2012.07.02

Certificate number: DGM – 786
Certificate type: EC Design Examination Certificate

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Reshapeable tip

REF Number	Date for first CE Mark
Hy-N-R-ST-018-D-L	2015.12.08
Hy-N-R-ST-025-D-L	2012.07.02
Hy-N-R-ST-032-D-L	2012.07.02
Hy-N-R-ST-035-D-L	2012.07.02
Hy-N-R-ST-038-D-L	2012.07.02
Hy-N-R-ST-025-H-L	2012.07.02
Hy-N-R-ST-032-H-L	2012.07.02
Hy-N-R-ST-035-H-L	2012.07.02
Hy-N-R-ST-038-H-L	2012.07.02
Hy-N-R-SO-018-D-L	2015.12.08
Hy-N-R-SO-025-D-L	2012.07.02
Hy-N-R-SO-032-D-L	2012.07.02
Hy-N-R-SO-035-D-L	2012.07.02
Hy-N-R-SO-038-D-L	2012.07.02
Hy-N-R-SO-025-H-L	2012.07.02
Hy-N-R-SO-032-H-L	2012.07.02
Hy-N-R-SO-035-H-L	2012.07.02
Hy-N-R-SO-038-H-L	2012.07.02
Hy-N-R-F-018-D-L	2015.12.08
Hy-N-R-F-025-D-L	2012.07.02
Hy-N-R-F-032-D-L	2012.07.02
Hy-N-R-F-035-D-L	2012.07.02
Hy-N-R-F-038-D-L	2012.07.02
Hy-N-R-F-025-H-L	2012.07.02
Hy-N-R-F-032-H-L	2012.07.02
Hy-N-R-F-035-H-L	2012.07.02
Hy-N-R-F-038-H-L	2012.07.02

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Angled tip

REF Number	Date for first CE Mark
Hy-N-A-ST-018-D-L	2015.12.08
Hy-N-A-ST-025-D-L	2012.07.02
Hy-N-A-ST-032-D-L	2012.07.02
Hy-N-A-ST-035-D-L	2012.07.02
Hy-N-A-ST-038-D-L	2012.07.02
Hy-N-A-ST-025-H-L	2012.07.02
Hy-N-A-ST-032-H-L	2012.07.02
Hy-N-A-ST-035-H-L	2012.07.02
Hy-N-A-ST-038-H-L	2012.07.02
Hy-N-A-SO-018-D-L	2015.12.08
Hy-N-A-SO-025-D-L	2012.07.02
Hy-N-A-SO-032-D-L	2012.07.02
Hy-N-A-SO-035-D-L	2012.07.02
Hy-N-A-SO-038-D-L	2012.07.02
Hy-N-A-SO-025-H-L	2012.07.02
Hy-N-A-SO-032-H-L	2012.07.02
Hy-N-A-SO-035-H-L	2012.07.02
Hy-N-A-SO-038-H-L	2012.07.02
Hy-N-A-F-018-D-L	2015.12.08
Hy-N-A-F-025-D-L	2012.07.02
Hy-N-A-F-032-D-L	2012.07.02
Hy-N-A-F-035-D-L	2012.07.02
Hy-N-A-F-038-D-L	2012.07.02
Hy-N-A-F-025-H-L	2012.07.02
Hy-N-A-F-032-H-L	2012.07.02
Hy-N-A-F-035-H-L	2012.07.02
Hy-N-A-F-038-H-L	2012.07.02

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Double Ended tip

REF Number	Date for first CE Mark
DE-Hy-N-A-ST-S-SO-035-H-L	2013.06.12

General product codes

Allowed Optional variants

A suffix **AAYY** can if needed be added at the end of the above listed REF numbers:

Purpose, handle national label requirements and identification of different distributors in specific countries

- **Hy** is Hydrophilic
- **N** is Nitinol Steel
- **A** is angled tip
- **R** is reshapable tip
- **S** is straight tip
- **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 the total length of the guide wire in the range from 30 cm. to 260 cm.
- **AA** is country abbreviation written with 2 characters.
- **YY** is a number from 01 to 99 in cases were REF number is to identify specific distributors in specific countries.

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