



**LÆGEMIDDELSTYRELSEN**  
DANISH MEDICINES AGENCY



## Free Sales Certificate

The Danish Medicines Agency hereby certifies that the company has its registered place of business in Denmark:

**SP Medical A/S**  
**Møllevej 1**  
**DK-4653 Karise**  
**Denmark**

Medical devices specified in the attached list which are CE marked in conformity with Directives 93/42/EEC and 90/385/EEC may be marketed in Denmark/EU and exported without any approval from the Danish Medicines Agency in accordance with article 120 of the Medical Device Regulation (Council Regulation 2017/745).



Valid from: **19 June 2021**  
Valid Until: **14 September 2022**

*AK Christensen*

**Astrid Kolind Christensen**



# Poseidon

## Hydrophilic Nitinol Guide Wire

### Product list

The following products are covered by EC Certificate 1000457530-PA-NA-DNK.

#### Item codes – Poseidon Hydrophilic Nitinol Guide Wire (Straight tip)

Item code	Class	Date for first CE mark
Hy-N-S-ST-018-D-L	III	2012-07-02
Hy-N-S-ST-025-D-L	III	2012-07-02
Hy-N-S-ST-032-D-L	III	2012-07-02
Hy-N-S-ST-035-D-L	III	2012-07-02
Hy-N-S-ST-038-D-L	III	2012-07-02
Hy-N-S-ST-025-H-L	III	2012-07-02
Hy-N-S-ST-032-H-L	III	2012-07-02
Hy-N-S-ST-035-H-L	III	2012-07-02
Hy-N-S-ST-038-H-L	III	2012-07-02
Hy-N-S-SO-018-D-L	III	2015-12-08
Hy-N-S-SO-025-D-L	III	2012-07-02
Hy-N-S-SO-032-D-L	III	2012-07-02
Hy-N-S-SO-035-D-L	III	2012-07-02
Hy-N-S-SO-038-D-L	III	2012-07-02
Hy-N-S-SO-025-H-L	III	2012-07-02
Hy-N-S-SO-032-H-L	III	2012-07-02
Hy-N-S-SO-035-H-L	III	2012-07-02
Hy-N-S-SO-038-H-L	III	2012-07-02
Hy-N-S-F-018-D-L	III	2015-12-08
Hy-N-S-F-025-D-L	III	2012-07-02
Hy-N-S-F-032-D-L	III	2012-07-02
Hy-N-S-F-035-D-L	III	2012-07-02
Hy-N-S-F-038-D-L	III	2012-07-02
Hy-N-S-F-025-H-L	III	2012-07-02
Hy-N-S-F-032-H-L	III	2012-07-02
Hy-N-S-F-035-H-L	III	2012-07-02
Hy-N-S-F-038-H-L	III	2012-07-02

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





**Item codes – Poseidon Hydrophilic Nitinol Guide Wire (Reshapeable tip)**

Item code	Class	Date for first CE mark
Hy-N-R-ST-018-D-L	III	2015-12-08
Hy-N-R-ST-025-D-L	III	2012-07-02
Hy-N-R-ST-032-D-L	III	2012-07-02
Hy-N-R-ST-035-D-L	III	2012-07-02
Hy-N-R-ST-038-D-L	III	2012-07-02
Hy-N-R-ST-025-H-L	III	2012-07-02
Hy-N-R-ST-032-H-L	III	2012-07-02
Hy-N-R-ST-035-H-L	III	2012-07-02
Hy-N-R-ST-038-H-L	III	2012-07-02
Hy-N-R-SO-018-D-L	III	2015-12-08
Hy-N-R-SO-025-D-L	III	2012-07-02
Hy-N-R-SO-032-D-L	III	2012-07-02
Hy-N-R-SO-035-D-L	III	2012-07-02
Hy-N-R-SO-038-D-L	III	2012-07-02
Hy-N-R-SO-025-H-L	III	2012-07-02
Hy-N-R-SO-032-H-L	III	2012-07-02
Hy-N-R-SO-035-H-L	III	2012-07-02
Hy-N-R-SO-038-H-L	III	2012-07-02
Hy-N-R-F-018-D-L	III	2015-12-08
Hy-N-R-F-025-D-L	III	2012-07-02
Hy-N-R-F-032-D-L	III	2012-07-02
Hy-N-R-F-035-D-L	III	2012-07-02
Hy-N-R-F-038-D-L	III	2012-07-02
Hy-N-R-F-025-H-L	III	2012-07-02
Hy-N-R-F-032-H-L	III	2012-07-02
Hy-N-R-F-035-H-L	III	2012-07-02
Hy-N-R-F-038-H-L	III	2012-07-02

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





**Item codes – Poseidon Hydrophilic Nitinol Guide Wire (Angled tip)**

Item code	Class	Date for first CE mark
Hy-N-A-ST-018-D-L	III	2015-12-08
Hy-N-A-ST-025-D-L	III	2012-07-02
Hy-N-A-ST-032-D-L	III	2012-07-02
Hy-N-A-ST-035-D-L	III	2012-07-02
Hy-N-A-ST-038-D-L	III	2012-07-02
Hy-N-A-ST-025-H-L	III	2012-07-02
Hy-N-A-ST-032-H-L	III	2012-07-02
Hy-N-A-ST-035-H-L	III	2012-07-02
Hy-N-A-ST-038-H-L	III	2012-07-02
Hy-N-A-SO-018-D-L	III	2015-12-08
Hy-N-A-SO-025-D-L	III	2012-07-02
Hy-N-A-SO-032-D-L	III	2012-07-02
Hy-N-A-SO-035-D-L	III	2012-07-02
Hy-N-A-SO-038-D-L	III	2012-07-02
Hy-N-A-SO-025-H-L	III	2012-07-02
Hy-N-A-SO-032-H-L	III	2012-07-02
Hy-N-A-SO-035-H-L	III	2012-07-02
Hy-N-A-SO-038-H-L	III	2012-07-02
Hy-N-A-F-018-D-L	III	2015-12-08
Hy-N-A-F-025-D-L	III	2012-07-02
Hy-N-A-F-032-D-L	III	2012-07-02
Hy-N-A-F-035-D-L	III	2012-07-02
Hy-N-A-F-038-D-L	III	2012-07-02
Hy-N-A-F-025-H-L	III	2012-07-02
Hy-N-A-F-032-H-L	III	2012-07-02
Hy-N-A-F-035-H-L	III	2012-07-02
Hy-N-A-F-038-H-L	III	2012-07-02

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





### Item codes – Poseidon Hydrophilic Nitinol Guide Wire (Double ended)

Item code	Class	Date for first CE mark
DE-Hy-N-A-ST-S-SO-035-H-L	III	2013-06-12

A suffix AYY can if needed be added at the end of the above listed REF numbers.

### Description of Item Code

The item code for the Poseidon Hydrophilic Nitinol Guide Wire is composed as follows:

Poseidon - Straight, reshapable and angled tip

- **HY-N-S/R/A-ST/SO/F-Oxx-D/H-L** (e.g. HY-N-A-ST-035-D-L)

Poseidon - Double ended

- **DE-Hy-N-A-ST-S-SO-035-H-L**

Each code element is explained in the following table:

Code	Description	Code	Description
DE	Double ended	0xx	Diameter of the Guide Wire. Available in: <ul style="list-style-type: none"> <li>▪ 018 = 0.018"</li> <li>▪ 025 = 0.025"</li> <li>▪ 032 = 0.032"</li> <li>▪ 035 = 0.035"</li> <li>▪ 038 = 0.038"</li> <li>▪ Double ended only exist as 035</li> </ul>
Hy	Hydrophilic coating	D	Standard shaft
N	Nitinol core	H	Stiff shaft
ST	Standard tip stiffness	L	Length of the Guide Wire. Available in: <ul style="list-style-type: none"> <li>▪ 30 – 260 cm</li> </ul>
SO	Soft tip stiffness		
F	Floppy tip stiffness		

### Allowed optional variants

A suffix AYY can if needed be added at the end of the REF numbers:

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 REF number is to identify specific distributors in specific countries.

