



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 the Medical Device Regulation (Council Regulation 2017/745) may be manufactured and marketed in Denmark/EU and exported without any approval from the Danish Medicines Agency.



Valid from: **22 August 2022**
Valid Until: **22 August 2024**

Signe Lorentsen
Signe Lorentsen



Poseidon

Hydrophilic Nitinol Guide Wire

Product list

The following products are covered by EU Certificate IZ 2320977-2.

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

Item code	Class	Basic UDI-DI	Date for first CE mark
Hy-N-S-ST-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-ST-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-SO-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-S-F-038-H-L	III	5710086-GWPOLZ	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	Basic UDI-DI	Date for first CE mark
Hy-N-R-ST-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-ST-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-SO-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-R-F-038-H-L	III	5710086-GWPOLZ	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	Basic UDI-DI	Date for first CE mark
Hy-N-A-ST-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-025-D-L	III	5710086-GWPOLZ	2012-07-02





Item code	Class	Basic UDI-DI	Date for first CE mark
Hy-N-A-ST-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-ST-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-SO-038-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-018-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-025-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-032-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-035-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-038-D-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-025-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-032-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-035-H-L	III	5710086-GWPOLZ	2012-07-02
Hy-N-A-F-038-H-L	III	5710086-GWPOLZ	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	Basic UDI-DI	Date for first CE mark
DE-Hy-N-A-ST-S-SO-035-H-L	III	5710086-GWPOLZ	2013-06-12

A suffix AAYY 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	Oxx	Diameter of the guide wire: <ul style="list-style-type: none"> ▪ 018 = 0.018" ▪ 025 = 0.025" ▪ 032 = 0.032" ▪ 035 = 0.035" ▪ 038 = 0.038" ▪ Double-ended only exist as 035
Hy	Hydrophilic coating	D	Standard shaft
N	Nitinol core	H	Stiff shaft
S	Straight tip	L	Length of the guide wire: <ul style="list-style-type: none"> ▪ 30 – 260 cm
R	Reshapable tip		
A	Angled tip		
ST	Standard tip stiffness		
SO	Soft tip stiffness		
F	Floppy tip stiffness		

Allowed optional variants

A suffix AYYY 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 where REF number is to identify specific distributors in specific countries.

