



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: **02 August 2024**
Valid Until: **02 August 2026**

Lise Roving Kristiansen
Student Assistant



We have been informed that the products specified below, are manufactured at the site:

SP Medical Sp. Z o.o.
Ul. Ceramiczna 2,
PL-98-220 Zdunska Wola

On behalf of

SP Medical A/S
Møllevvej 1,
DK-4653 Karise

Poseidon

Hydrophilic Nitinol Guide Wire

Product list

The following products are covered by EU Certificate HZ 2320977-1.

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 | 2015-12-08 |
| 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 | 2015-12-08 |



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|------------------|-------|----------------|------------------------|
| 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 | 2015-12-08 |
| 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 | 2015-12-08 |
| 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 | 2015-12-08 |
| 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 |





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|------------------|-------|----------------|------------------------|
| 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 | 2015-12-08 |
| Hy-N-A-ST-025-D-L | III | 5710086-GWPOLZ | 2012-07-02 |
| 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 | 2015-12-08 |
| 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 | 2015-12-08 |
| 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 AYYY 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 AYYY 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: |
| Hy | Hydrophilic coating | | <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 |
| N | Nitinol core | | |
| S | Straight tip | | |
| R | Reshapable tip | | |
| A | Angled tip | | |
| ST | Standard tip stiffness | D | Standard shaft |
| SO | Soft tip stiffness | H | Stiff shaft |
| F | Floppy tip stiffness | L | Length of the guide wire: |
| | | | <ul style="list-style-type: none"> ▪ 30 – 260 cm |

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.

