



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: **25 November 2022**
Valid Until: **25 November 2024**

Signe Lorentsen
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Poseidon URO

Guide Wire

Product list

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

Item codes – Poseidon URO Guide Wire (Straight tip)

Item code	Class	Basic UDI-DI
URO-Hy-N-S-ST-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-ST-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-SO-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-SO-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-SO-032-D-L	Ila	5710086-GWPUMD
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URO-Hy-N-S-SO-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-S-F-038-H-L	Ila	5710086-GWPUMD

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





Item codes – Poseidon URO Guide Wire (Reshapeable tip)

Item code	Class	Basic UDI-DI
URO-Hy-N-R-ST-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-ST-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-SO-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-R-F-038-H-L	Ila	5710086-GWPUMD

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

Item codes – Poseidon URO Guide Wire (Angled tip)

Item code	Class	Basic UDI-DI
URO-Hy-N-A-ST-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-025-D-L	Ila	5710086-GWPUMD





Item code	Class	Basic UDI-DI
URO-Hy-N-A-ST-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-ST-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-SO-038-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-018-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-025-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-032-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-035-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-038-D-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-025-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-032-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-035-H-L	Ila	5710086-GWPUMD
URO-Hy-N-A-F-038-H-L	Ila	5710086-GWPUMD

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

Item codes – Poseidon URO Guide Wire (Double ended)

Item code	Class	Basic UDI-DI
URO-DE-Hy-N-A-ST-S-SO-035-H-L	Ila	5710086-GWPUMD

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 URO Guide Wire is composed as follows:





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

Each code element is explained in the following table:

Code	Description	Code	Description
URO	Poseidon URO Guide Wire	F	Floppy tip stiffness
DE	Double ended	0xx	Diameter of the guide wire: <ul style="list-style-type: none"> ▪ 018: 0.018" (0.46 mm) ▪ 025: 0.025" (0.64 mm) ▪ 032: 0.032" (0.82 mm) ▪ 035: 0.035" (0.89 mm) ▪ 038: 0.038" (0.97 mm)
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		

By inserting values, the item code is transformed into the specific REF number, e.g., URO-Hy-N-A-ST-035-D-150 for a guide wire with a length of 150 cm.

Allowed optional variants

With purpose of handling national label requirements and identification of different distributors in specific countries, a suffix AAYY can, if needed, be added at the end of the REF numbers:

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.

