



## 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 September 2024**  
Valid Until: **25 September 2026**

**Rebecca Elnif Andersen**



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 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	Date for first CE mark
URO-Hy-N-S-ST-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-ST-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-032-D-L	Ila	5710086-GWPUMD	2022-07-07
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URO-Hy-N-S-SO-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-SO-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-018-D-L	Ila	5710086-GWPUMD	2022-07-07





Item code	Class	Basic UDI-DI	Date for first CE mark
URO-Hy-N-S-F-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-S-F-038-H-L	Ila	5710086-GWPUMD	2022-07-07

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	Date for first CE mark
URO-Hy-N-R-ST-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-ST-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-SO-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-035-D-L	Ila	5710086-GWPUMD	2022-07-07





Item code	Class	Basic UDI-DI	Date for first CE mark
URO-Hy-N-R-F-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-R-F-038-H-L	Ila	5710086-GWPUMD	2022-07-07

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	Date for first CE mark
URO-Hy-N-A-ST-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-ST-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-032-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-SO-038-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-018-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-025-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-032-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-035-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-038-D-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-025-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-032-H-L	Ila	5710086-GWPUMD	2022-07-07





Item code	Class	Basic UDI-DI	Date for first CE mark
URO-Hy-N-A-F-035-H-L	Ila	5710086-GWPUMD	2022-07-07
URO-Hy-N-A-F-038-H-L	Ila	5710086-GWPUMD	2022-07-07

A suffix AYYY 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	Date for first CE mark
URO-DE-Hy-N-A-ST-S-SO-035-H-L	Ila	5710086-GWPUMD	2022-07-07

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 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	Oxx	Diameter of the guide wire: <ul style="list-style-type: none"> <li>▪ 018: 0.018" (0.46 mm)</li> <li>▪ 025: 0.025" (0.64 mm)</li> <li>▪ 032: 0.032" (0.82 mm)</li> <li>▪ 035: 0.035" (0.89 mm)</li> <li>▪ 038: 0.038" (0.97 mm)</li> </ul>
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"> <li>▪ 30 – 260 cm</li> </ul>
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 AYYY 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.

