

## Regulatory Information December 2022

### Poseidon URO Guide Wire Class IIa

SP Medical's newest product program, Poseidon URO Guide Wire, has passed assessment according to EU Regulation 2017/745 (MDR).

#### Intended purpose

Poseidon URO Guide Wire is intended to facilitate the placement of interventional devices during diagnostic/therapeutic endourological and gastrointestinal procedures.

#### Classification

Poseidon URO Guide Wire program is based on Poseidon Hydrophilic Nitinol Guide Wire program but is **classified IIa**.

#### Quaracteristics

Poseidon URO Guide Wire has same characteristics and qualities as Poseidon Hydrophilic Nitinol Guide Wire, e.g.:

- High radiopacity
- Nitinol core for kink resistance
- Hydrophilic surface for reduced friction

#### Product programme

Poseidon URO Guide Wire is available in same sizes and variants as Poseidon Hydrophilic Nitinol Guide Wire. Direct link to Poseidon URO brochure: <https://sp-medical.com/media/7599/gw-poseidon-uro-2022.pdf>

#### IFU

See SP Medical's website: <https://sp-medical.com/downloads/instructions-for-use>

#### Shelf life

Shelf life is 3 years

#### Certificate no.: HZ 2320977-1

- Certified by TÜV Rheinland®
- Valid date: 07-07-2022
- Expiry date: 18-11-2026

Download the certificate from SP Medical's website: <https://sp-medical.com/downloads/certificates/>



## Label examples

Peel pouch label:

**Poseidon URO**  
Guide Wire  
Straight standard tip, standard shaft

150 cm  
0.035" (0.89 mm)

**REF** URO-HY-N-S-ST-035-D-150  
**LOT** 77771  
PL 2022-07  
2025-06  
**MD**  
**UDI**

**CE 0197**  
SP Medical A/S  
Møllevvej 1  
DK-4653 Karise  
Tel: +45 56 76 60 00  
www.sp-medical.com

Standard shaft  
1

STERILE EO  
2

GWPU-LS-P1-S.v01

(01)05710086041501(17)250630(10)77771

5 pcs. product box label

**Poseidon URO**  
Guide Wire  
Straight standard tip, standard shaft

150 cm  
0.035" (0.89 mm)

**REF** URO-HY-N-S-ST-035-D-150  
**LOT** 77771  
PL 2022-07  
2025-06  
**MD**  
**UDI**

**CE 0197**  
SP Medical A/S  
Møllevvej 1  
DK-4653 Karise  
Tel: +45 56 76 60 00  
www.sp-medical.com

Standard shaft  
5

Standard shaft  
5

GWPU-LS-P2-Stia.v01

(01)45710086041509(17)250630(10)77771

**LOT** 77771  
**SP Medical**  
Guide Wire  
Straight standard tip, standard shaft  
150 cm  
0.035" (0.89 mm)  
**REF** URO-HY-N-S-ST-035-D-150

Shipper box label:

**Poseidon URO**  
Double Ended Guide Wire  
Angled standard tip, straight soft tip, stiff shaft

150 cm  
0.035" (0.89 mm)

**REF** URO-DE-HY-N-A-ST-S-SO-035-H-150  
**LOT** 77774  
PL 2022-07  
2025-06  
**MD**

**CE 0197**  
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STERILE EO

100 Pcs.

GWPU-LS-P3.v01