

## Regulatory Information August 2022

### Poseidon Hydrophilic Nitinol Guide Wire

Our Poseidon Hydrophilic Nitinol Guide Wire programme class III has passed the Technical Documentation Assessment according to EU Regulation 2017/745 (MDR).

**Certificate no.: IZ 2320977-2**

- Certified by TÜV Rheinland®
- Valid date: 07-07-2022
- Expiry date: 06-07-2027

**Main change to labels** (See attachment):

- Additional symbols
- Over time, more processes have been transferred to SP Medical's facility in Poland and therefore the country of manufacture symbol now states "PL". Final packaging, release of product and the legal manufacturing premises are still in Denmark.

**Main changes to IFU** (See our website: <https://sp-medical.com/downloads/instructions-for-use>)

- Additional symbols and symbol explanations
- Added instruction to check sterile barrier integrity
- Added instruction concerning reporting of serious incident
- Added Safety information including UDI-DI number and link to Eudamed

**Poseidon Hydrophilic Nitinol Guide Wire is still the same:**

- No changes to product design
- Poseidon Hydrophilic Nitinol Guide Wire is still Class III
- Shelf life is still 3 years
- Intended purpose is still the same but has got slightly new wording:

The guide wire is indicated for general intravascular and coronary arterial use to aid in the selective placement of interventional devices during diagnostic and / or therapeutic procedures.

The Technical Documentation Assessment Certificate and the Quality Management System Certificate can be downloaded from SP Medical's web site:

<http://sp-medical.com/downloads/certificates/>

In a transition period, products complying with both MDD and MDR certificates may be delivered.



## Label examples

Peel pouch label:

**Poseidon**  
D-E Hydrophilic Nitinol GW  
Angled standard tip, straight soft tip, stiff shaft

150 cm  
0.035" (0.89 mm)

**REF** DE-HY-N-A-ST-S-SO-035-H-150  
**LOT** EEEEE  
PL 2022-02  
MD 2025-01  
**UDI**

**STERILEEO**

**CE 0197**

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

GWPO-LS-P1-DE.v02

5 pcs. product box label

**Poseidon**  
Hydrophilic Nitinol Guide Wire  
Reshapable standard tip, standard shaft

150 cm  
0.038" (0.97 mm)

**REF** HY-N-R-ST-038-D-150  
**LOT** FFFFF  
PL 2022-02  
MD 2025-01  
**UDI**

**STERILEEO**

**CE 0197**

**SP Medical**  
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**Standard shaft**

**Standard shaft**

GWPO-LS-P2-Sta.v02

Shipper box label:

**Poseidon**  
Hydrophilic Nitinol Guide Wire  
Reshapeable soft tip, standard shaft

180 cm  
0.038" (0.97 mm)

**REF** HY-N-R-SO-038-D-180  
**LOT** 23456  
PL 2021-12  
MD 2024-11  
**UDI**

**STERILEEO**

**CE 0197**

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

**MD**

100 Pcs.

GWPO-LS-P3.v01