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

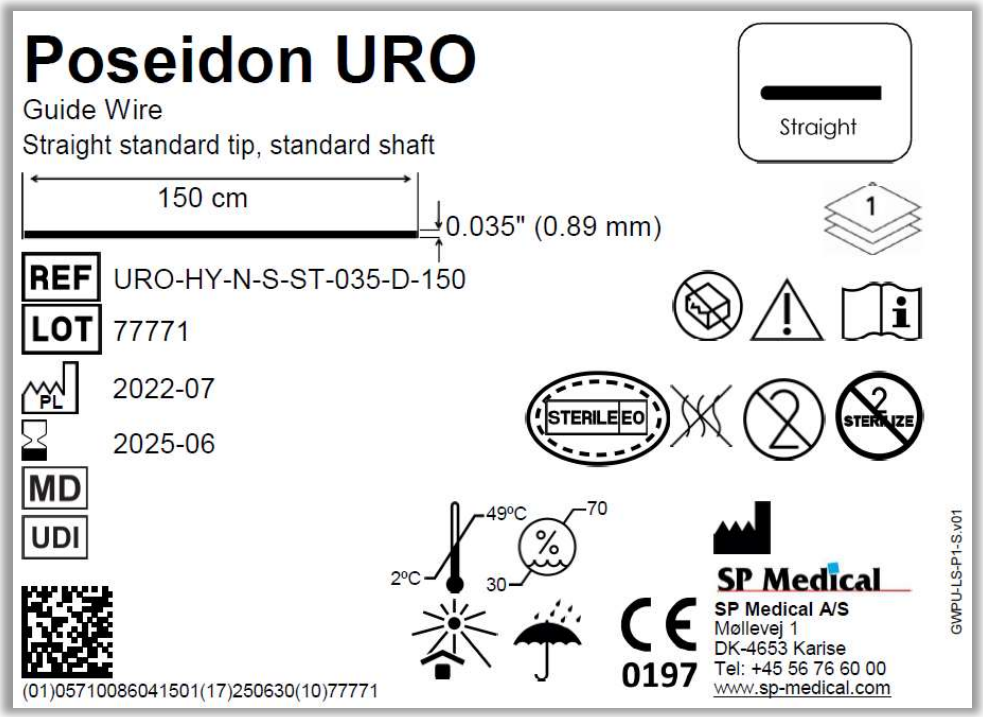
Certificate no.: HZ 2320977-1
- Certified by TÛV Rheinland®
- Valid date: 07-07-2022
- Expiry date: 18-11-2026

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

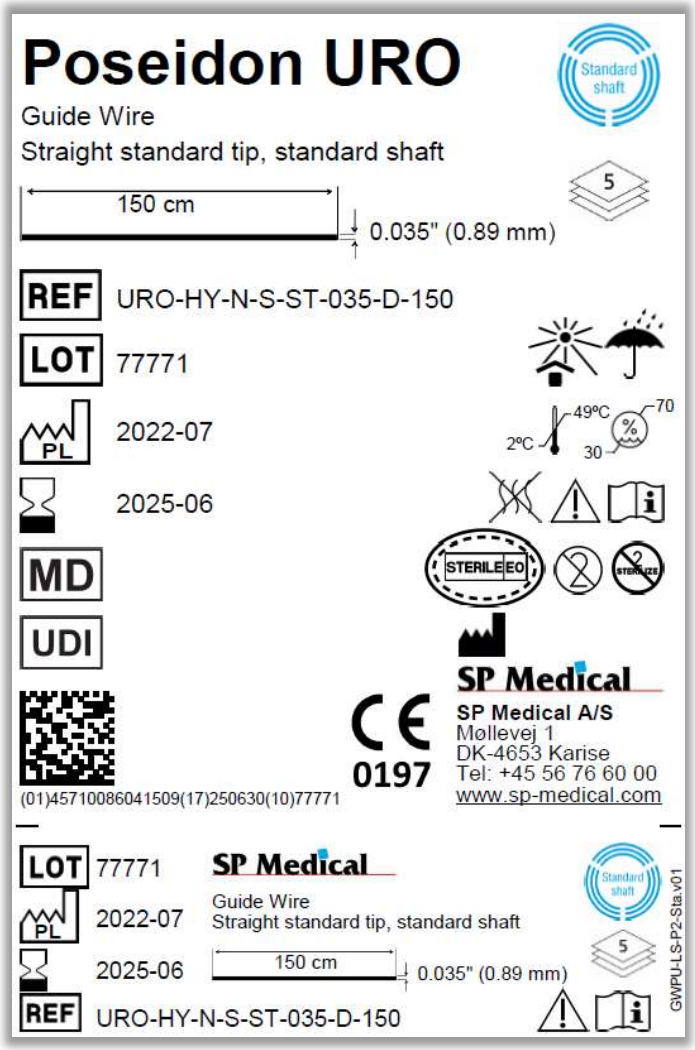
Attachment to Regulatory Information December 2022 from SP Medical

Label examples

Peel pouch label:



5 pcs. product box label



Shipper box label: