

Regulatory Information August 2022

Acccoat Standard Guide Wire

Our Acccoat Standard Guide Wire programme class IIa has passed assessment according to EU Regulation 2017/745 (MDR).

Certificate no.: HZ 2320977-1

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

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
- New wording of Intended purpose:

Intended purpose:

The Acccoat Standard Guide Wire is indicated for placement of interventional devices during diagnostic and/or therapeutic procedures in:

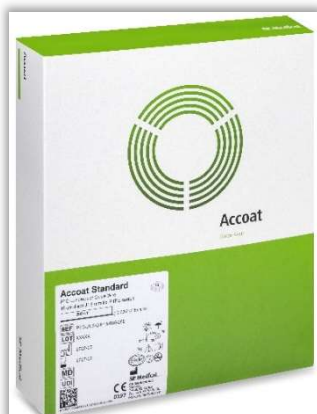
1. Peripheral vasculature procedures.
2. Endourologic procedures.

Acccoat Standard Guide Wire is still the same:

- No changes in manufacture or product design
- Acccoat Standard Guide Wire is still Class IIa
- Shelf life is still 5 years

The certificate can be downloaded from our web site: <http://sp-medical.com/downloads/certificates/>

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

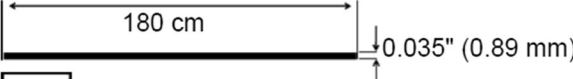


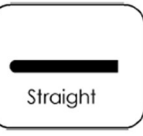
Label examples

Peel pouch label:

Accoat Standard

PTC-Lunderquist Guide Wire
10 cm distal straight tip, PTFE coated




Straight

REF PTC-S-C-F10-035-180


LOT XXXXX

PL 2022-03

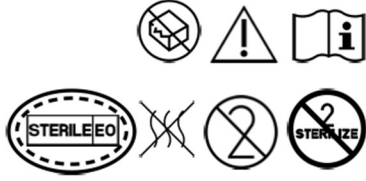
MD 2027-02


MD

UDI



(01)05710086003370(17)270228(10)XXXXX





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

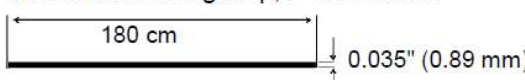
CE
0197


GWAS-LS-P1-S.v01

10 pcs. product box label

Accoat Standard

PTC-Lunderquist Guide Wire
10 cm distal straight tip, PTFE coated





REF PTC-S-C-F10-035-180


LOT XXXXX

PL 2022-03

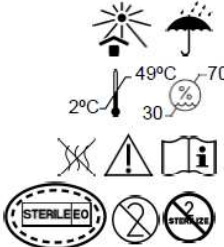
MD 2027-02


MD

UDI



(01)45710086003378(17)270228(10)XXXXX



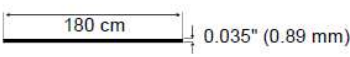


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SP Medical
SP Medical A/S
Møllevvej 1
DK-4653 Karise
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www.sp-medical.com

LOT XXXXX **SP Medical**

PL 2022-03 PTC-Lunderquist Guide Wire
10 cm distal straight tip, PTFE coated

MD 2027-02  0.035" (0.89 mm)

REF PTC-S-C-F10-035-180







GWAS-LS-P2.v01

Shipper box label:

Accoat Standard Guide Wire

10 cm distal straight tip, PTFE coated





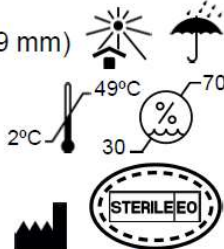
REF PTC-S-C-F10-035-180


LOT XXXXX

PL 2022-03

MD 2027-02

100 Pcs.





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Tel: +45 56 76 60 00
www.sp-medical.com

GWAS-LS-P3.v01