

Regulatory Information April 2022

Accoat Guide Wire

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

Certificate no.: IZ 2320977-1

- Certified by TÜV Rheinland®
- Valid date: 29-03-2022
- Expiry date: 28-03-2027

Main change to labels (See attachment 1):

- Additional symbols

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

- Additional symbols and symbol explanations
- Added instruction to check sterile barrier integrity
- Added instruction concerning reporting of serious incident
- Added link to Eudamed

Accoat Guide Wire is still the same:

- No changes to product design
- Accoat Guide Wire is still Class III
- Shelf life is still 5 years
- Intended use is still the same:

The Accoat 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.

Transition period:

- 6 months during which our customers may receive products that are manufactured under MDD.

The Technical Documentation Assessment Certificate and the Quality Management System Certificate can be downloaded from our web site:

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



Label examples

Peel pouch label:

Accoat Guide Wire
Seldinger Guide Wire
J3 mm tip, PTFE coated

260 cm
0.035" (0.89 mm)

REF J3-C-035-260
LOT BBBBB

2022-01
2026-12

MD
UDI

(01)05710086021367(17)261231(10)BBBBB

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

GWAC-LS-P1-Jv02

10 pcs. product box label

Shipper box label:

Accoat Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0,89 mm)

REF S-C-035-150
LOT 33333

2021-05
2026-04

MD
UDI

100 Pcs.

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

GWAC-LS-P3-v01

Accoat Guide Wire
Seldinger Guide Wire
Straight tip, PTFE coated

150 cm
0.035" (0.89 mm)

REF S-C-035-150
LOT AAAAA

2022-01
2026-12

MD
UDI

(01)45710086018693(17)261231(10)AAAAA

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LOT AAAAA **SP Medical**
Seldinger Guide Wire
Straight tip, PTFE coated

2022-01
2026-12

REF S-C-035-150

150 cm 0.035" (0.89 mm)

GWAC-LS-P2-Stia v02