

Regulatory Information February 2023

Champion PTCA Guide Wire

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

Certificate no.: IZ 2320977-3

- Certified by TÜV Rheinland®
- Valid date: 07-02-2023
- Expiry date: 06-02-2028

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

Champion PTCA Guide Wire is still the same:

- No changes to product design
- Champion PTCA Guide Wire is still Class III
- Shelf life is still 4 years
- Intended purpose is still the same but has got slightly new wording:

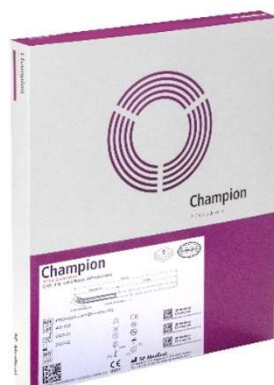
Intended purpose:

The Champion PTCA Guide Wire is indicated for general use in the coronary vasculature 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 website:

<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:

Champion
PTCA Guide Wire
CTO, straight tip, 3 gf

1

STERILE EO

195 cm

Hydrophilic

PTFE

3 cm radiopaque

0.014" (0.36 mm)

REF PTCA-CTO-S-HY-3-D-014-195

LOT 41470

2022-06

2026-05

MD

UDI

2°C

49°C

30

70

SP Medical
Champion

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5 pcs. product box label:

Champion
PTCA Guide Wire
CAR, J tip, floppy

5

STERILE EO

195 cm

Hydrophilic

PTFE

3 cm radiopaque

0.014" (0.36 mm)

REF PTCA-CAR-J-HY-F-D-014-195

LOT 41473

2022-06

2026-05

MD

UDI

2°C

49°C

30

70

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Champion

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SP Medical

LOT 41473

2022-06

2026-05

REF PTCA-CAR-J-HY-F-D-014-195

PTCA Guide Wire
CAR, J tip, floppy

195 cm

Hydrophilic

PTFE

3 cm radiopaque

0.014" (0.36 mm)

GWC2LS-P2-J-v01

Shipper box label:

Champion PTCA Guide Wire
CTO, straight tip, 3 gf

MD

195 cm

Hydrophilic

PTFE

3 cm radiopaque

0.014" (0.36 mm)

REF PTCA-CTO-S-HY-3-D-014-195

LOT 41470

2022-06

2026-05

50 Pcs.

2°C

49°C

30

70

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STERILE EO

GWC2LS-P3-S-v01

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.

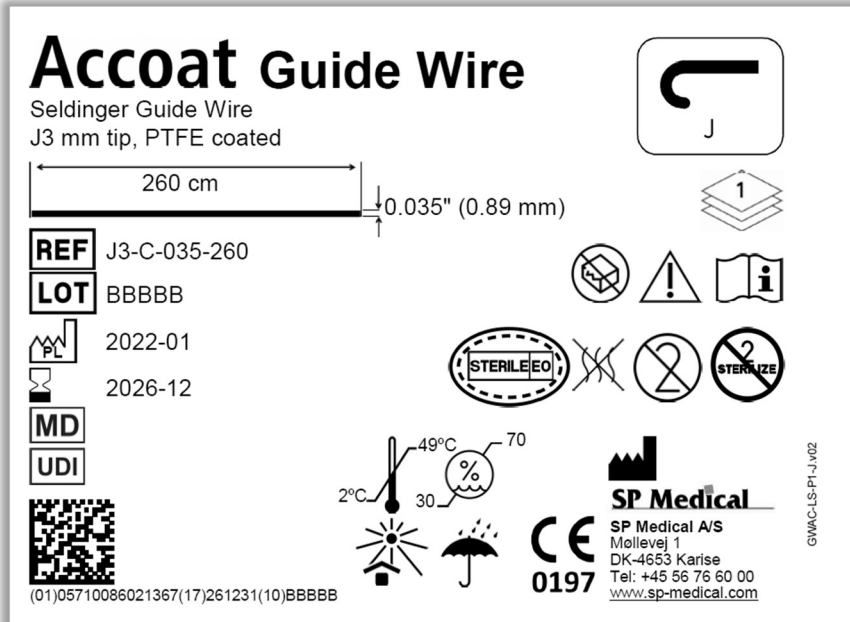
The Technical Documentation Assessment Certificate and the Quality Management System Certificate can be downloaded from our web site:

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



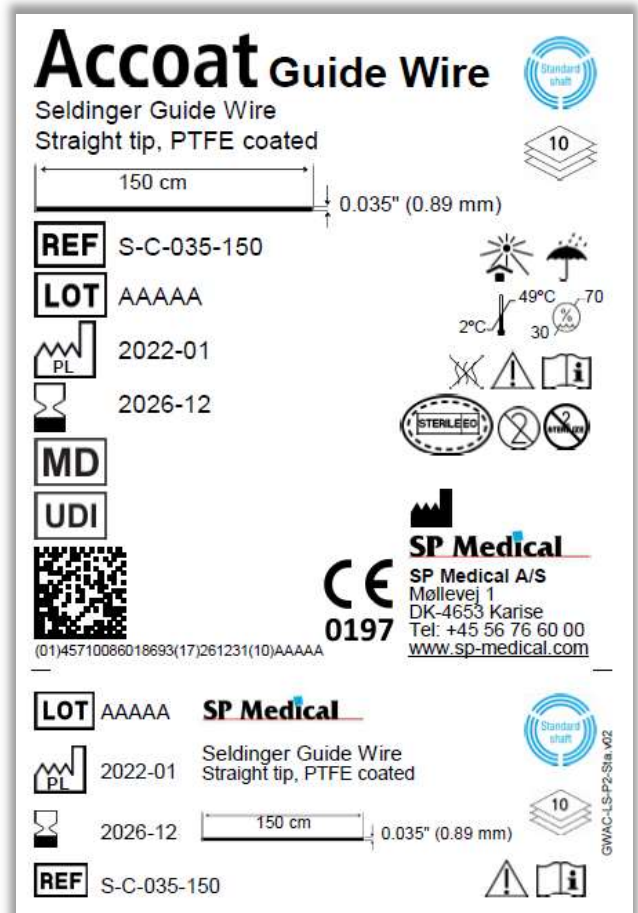
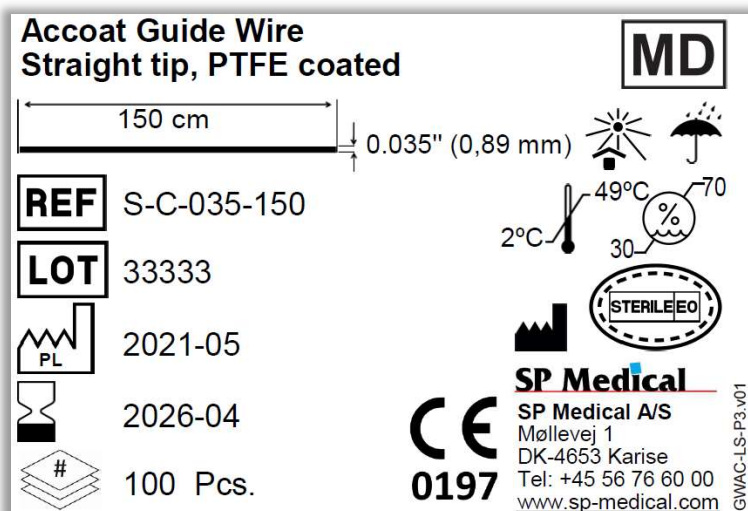
Label examples

Peel pouch label:



10 pcs. product box label

Shipper box label:



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
2022-02
2025-01
MD
UDI

STERILE EO

49°C 70
2°C 30

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GWPO-LS-P1-DE.v02

(01)05710086048036(17)250131(10)EEEE

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
2022-02
2025-01
MD
UDI

STERILE EO

49°C 70
2°C 30

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LOT FFFFF **SP Medical**
Hydrophilic Nitinol Guide Wire
Reshapable standard tip, standard shaft
150 cm 0.038" (0.97 mm)

REF HY-N-R-ST-038-D-150

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
2021-12
2024-11
100 Pcs.

STERILE EO

49°C 70
2°C 30

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GWPO-LS-P3.v01

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

180 cm
0.035" (0.89 mm)

REF PTC-S-C-F10-035-180
LOT XXXXX
2022-03
2027-02
MD
UDI

STERILE EO **STERILIZE**

49°C 70
2°C 30

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GWAS-LS-P1-S.v01

10 pcs. product box label

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

180 cm
0.035" (0.89 mm)

REF PTC-S-C-F10-035-180
LOT XXXXX
2022-03
2027-02
MD
UDI

STERILE EO **STERILIZE**

49°C 70
2°C 30

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LOT XXXXX **SP Medical**
PTC-Lunderquist Guide Wire
10 cm distal straight tip, PTFE coated
180 cm 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

180 cm
0.035" (0.89 mm)

REF PTC-S-C-F10-035-180
LOT XXXXX
2022-03
2027-02
MD

STERILE EO

49°C 70
2°C 30

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100 Pcs.

GWAS-LS-P3.v01