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 TÛV 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:

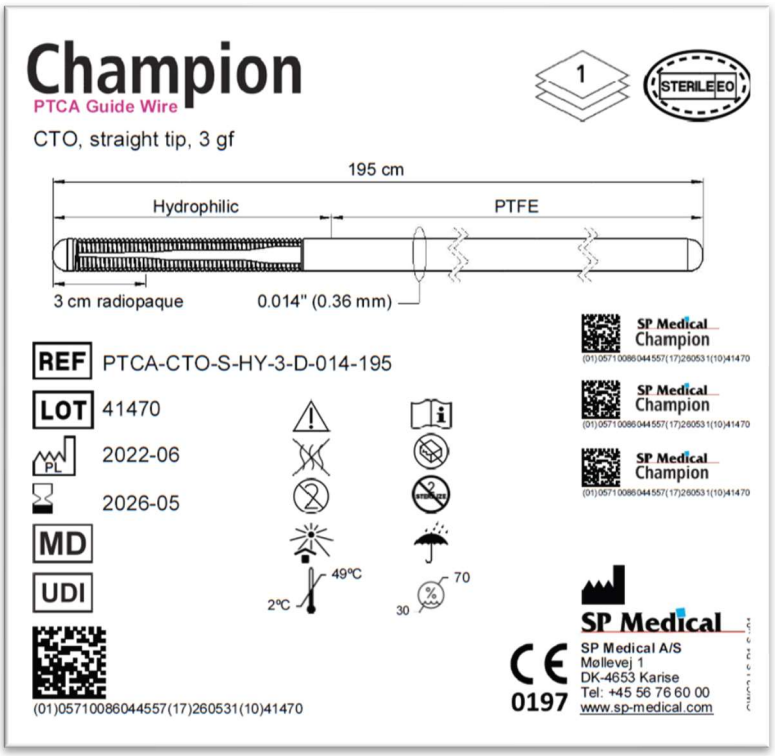
http://sp-medical.com/downloads/certificates/

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

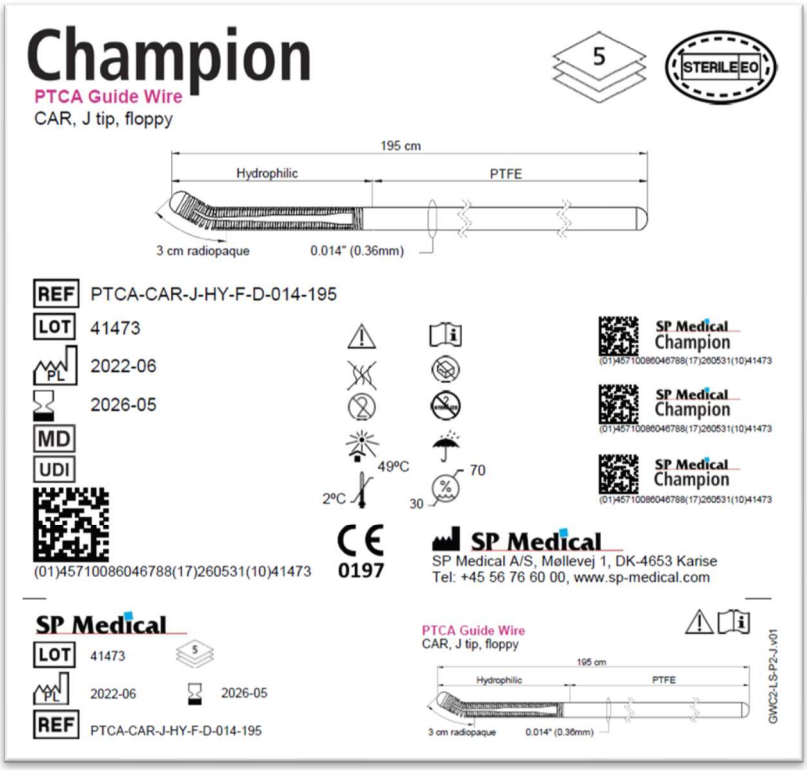
Attachment to Regulatory Information February 2023 from SP Medical

Label examples

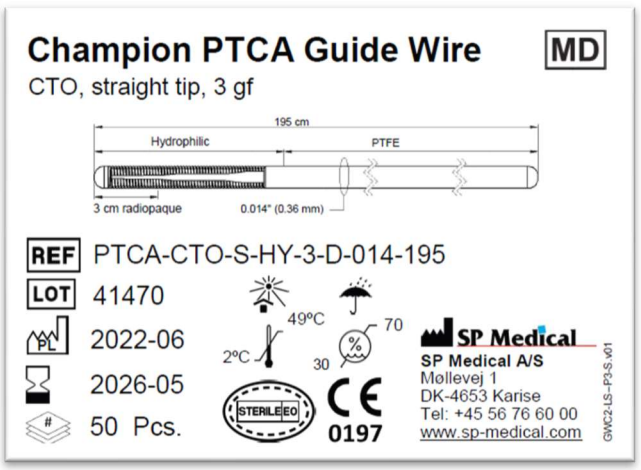
Peel pouch label:



5 pcs. product box label:



Shipper box label:



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 TÛV 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.

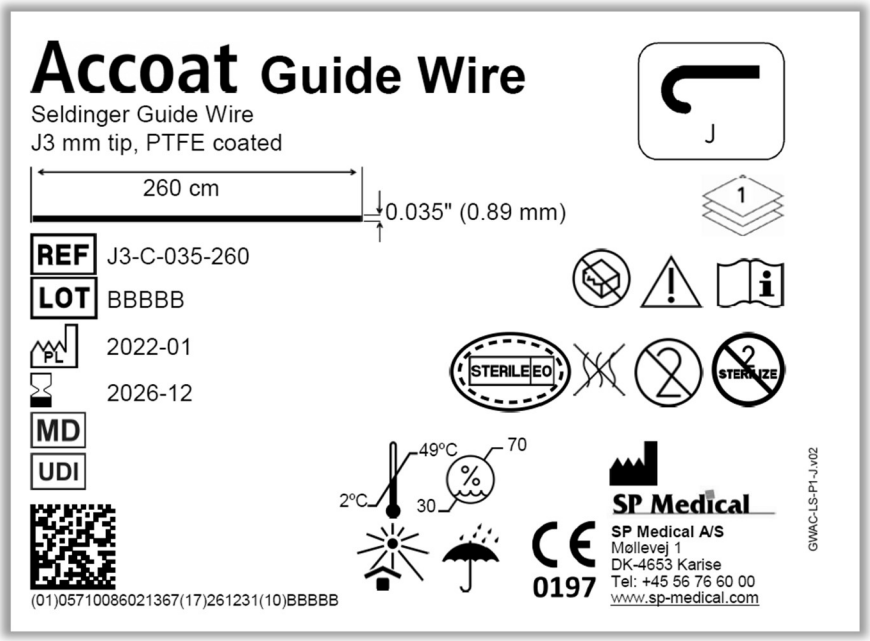
The Technical Documentation Assessment Certificate and the Quality Management System Certificate can be downloaded from our web site:

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

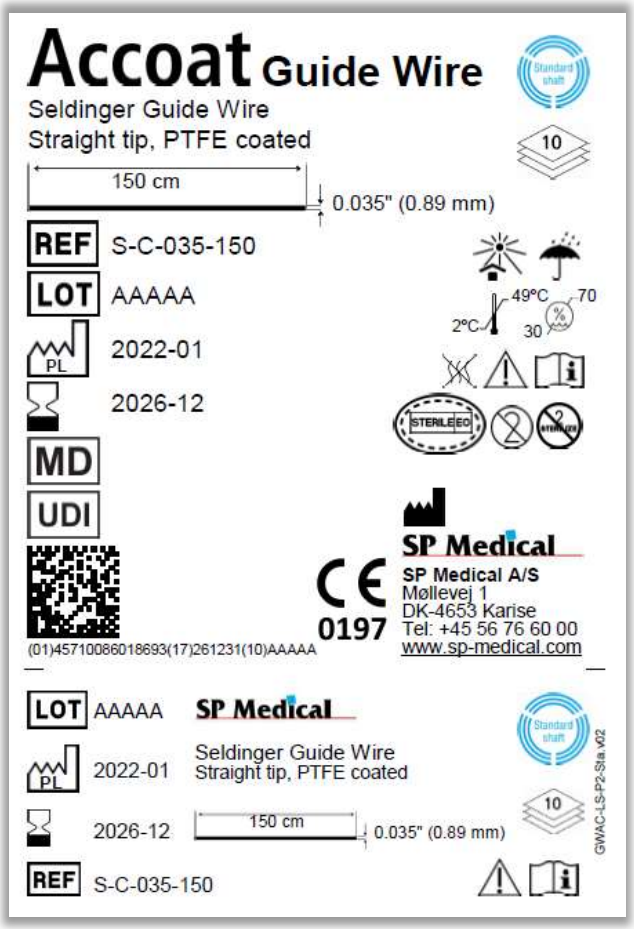
Attachment to Regulatory Information April 2022 from SP Medical

Label examples

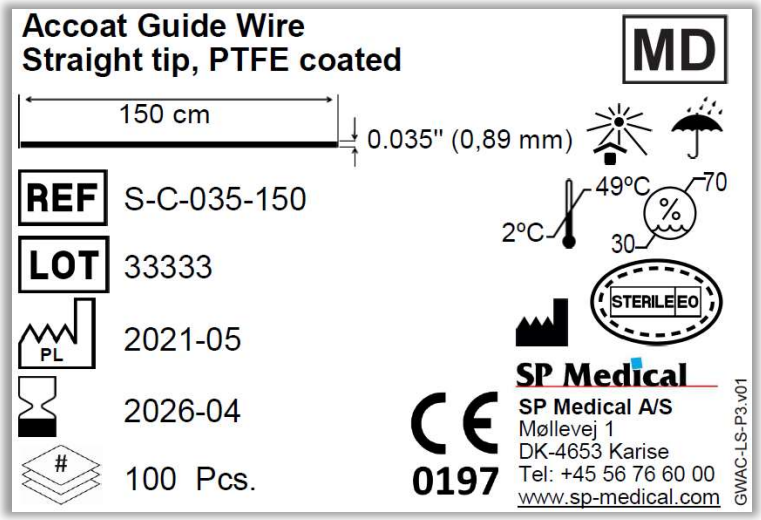
Peel pouch label:



10 pcs. product box label



Shipper box label:



SP Medical

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 TÛV 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:

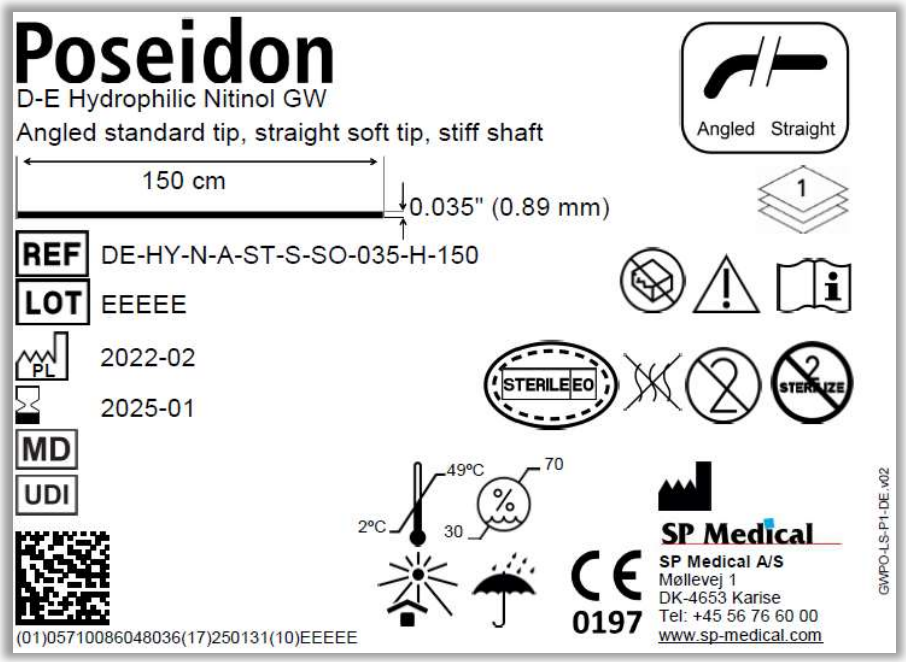
http://sp-medical.com/downloads/certificates/

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

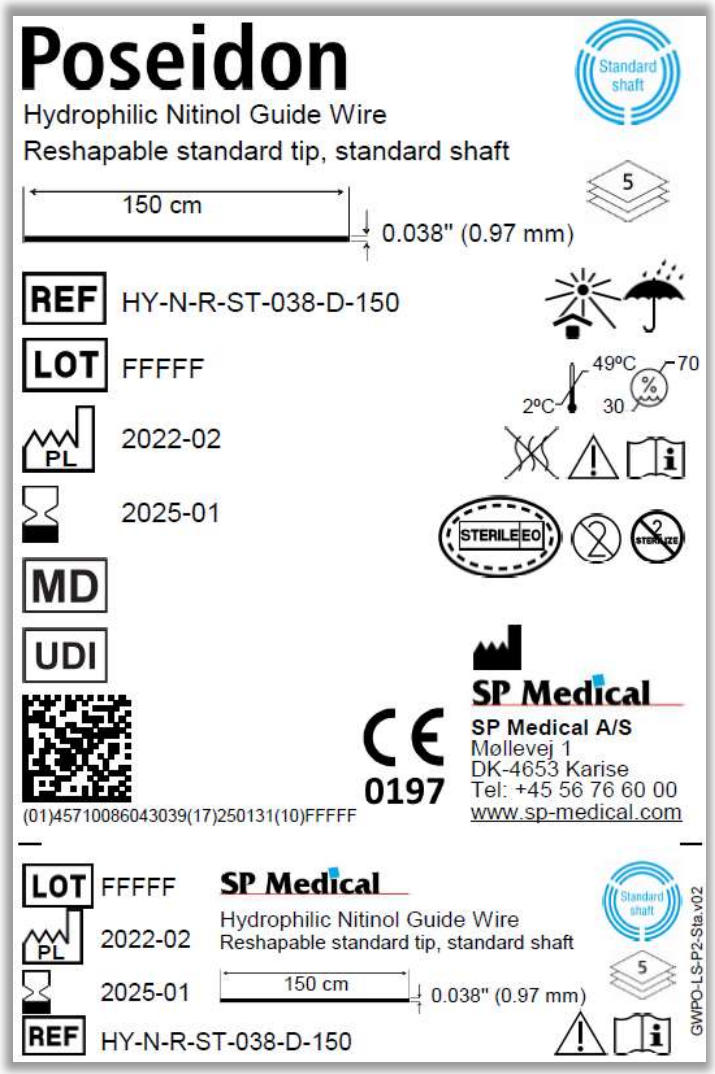
Attachment to Regulatory Information August 2022 from SP Medical

Label examples

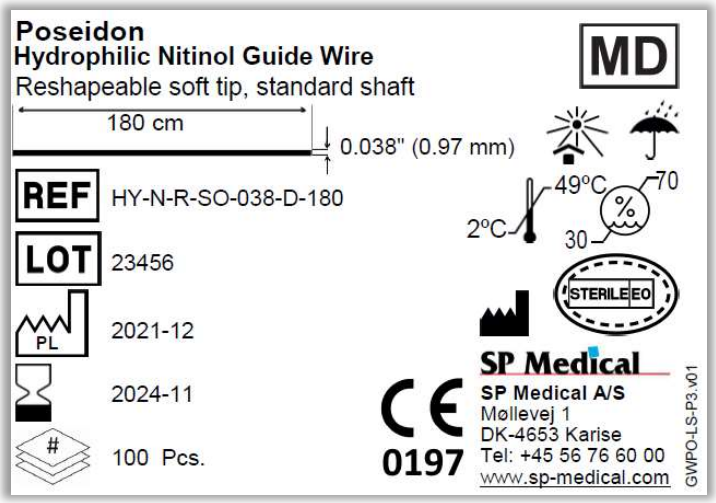
Peel pouch label:



5 pcs. product box label



Shipper box label:



Regulatory Information August 2022

Accoat Standard Guide Wire

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

Certificate no.: HZ 2320977-1
- Certified by TÛV 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 Accoat Standard Guide Wire is indicated for placement of interventional devices during diagnostic and/or therapeutic procedures in:
1. Peripheral vasculature procedures.
2. Endourologic procedures.

Accoat Standard Guide Wire is still the same:
- No changes in manufacture or product design
- Accoat Standard Guide Wire is still Class IIa
- Shelf life is still 5 years

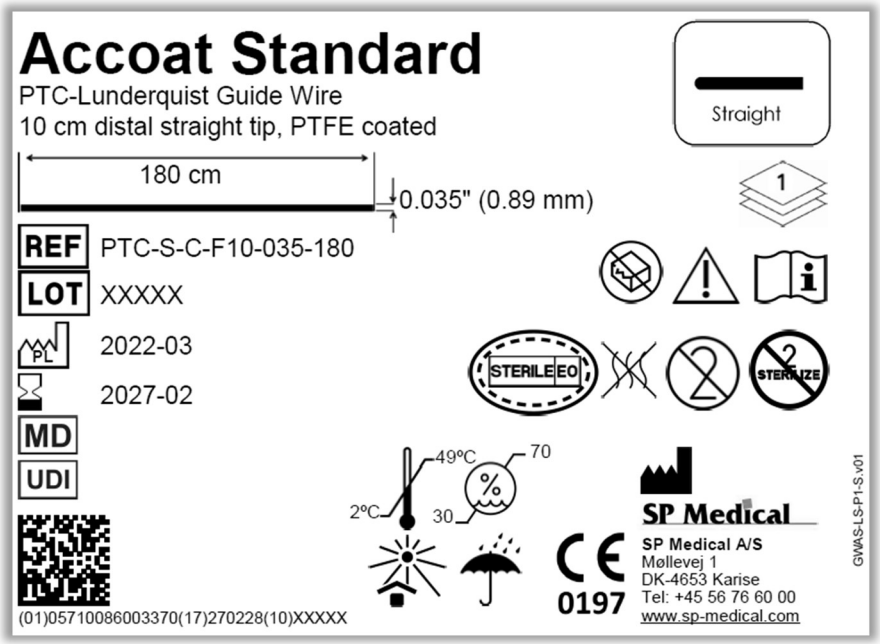
The certificate can be downloaded from our web site: http://sp-medical.com/downloads/certificates/

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

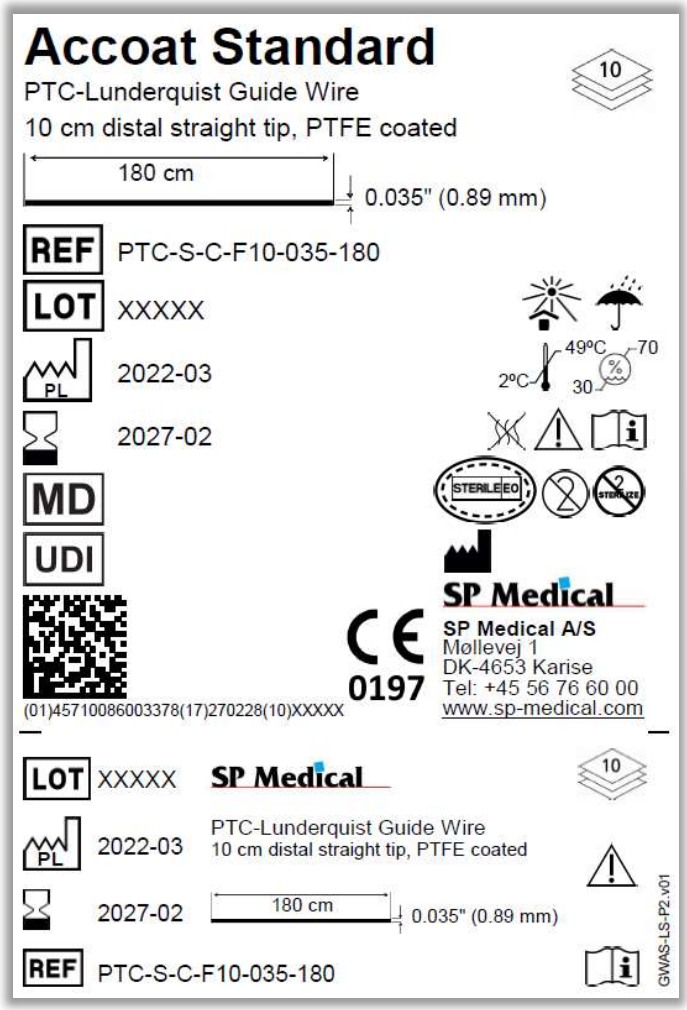
Attachment to Regulatory Information August 2022 from SP Medical

Label examples

Peel pouch label:



10 pcs. product box label



Shipper box label: