



Free Sales Certificate

The Danish Medicines Agency hereby certifies that the company has its registered place of business in Denmark:

SP Medical A/S
Møllevej 1
DK-4653 Karise
Denmark

Medical devices specified in the attached list which are CE marked in conformity with Directives 93/42/EEC and 90/385/EEC may be marketed in Denmark/EU and exported without any approval from the Danish Medicines Agency in accordance with article 120 of the Medical Device Regulation (Council Regulation 2017/745).



Valid from: **19 June 2021**
Valid Until: **19 June 2023**

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Accoat Standard

Guide Wire

Product list

The following products are covered by EC Certificate HD 2320977-1

Item codes – Lunderquist PTC

| Item code | Class | Date for first CE mark |
|-------------------|-------|------------------------|
| PTC-S-FI-025-L | Ila | 1998-08-26 |
| PTC-Jr-FI-025-L | Ila | 1998-08-26 |
| PTC-S-C-FI-025-L | Ila | 1998-08-26 |
| PTC-Jr-C-FI-025-L | Ila | 1998-08-26 |
| PTC-S-FI-035-L | Ila | 1998-08-26 |
| PTC-Jr-FI-035-L | Ila | 1998-08-26 |
| PTC-S-C-FI-035-L | Ila | 1998-08-26 |
| PTC-Jr-C-FI-035-L | Ila | 1998-08-26 |

Item codes – Schüller PTC

| Item code | Class | Date for first CE mark |
|-----------------------------|-------|------------------------|
| PTC-SCH-S-FI-L1-L2-025-L | Ila | 1998-08-26 |
| PTC-SCH-Jr-FI-L1-L2-025-L | Ila | 1998-08-26 |
| PTC-SCH-S-C-FI-L1-L2-025-L | Ila | 1998-08-26 |
| PTC-SCH-Jr-C-FI-L1-L2-025-L | Ila | 1998-08-26 |
| PTC-SCH-S-FI-L1-L2-035-L | Ila | 1998-08-26 |
| PTC-SCH-Jr-FI-L1-L2-035-L | Ila | 1998-08-26 |
| PTC-SCH-S-C-FI-L1-L2-035-L | Ila | 1998-08-26 |
| PTC-SCH-Jr-C-FI-L1-L2-035-L | Ila | 1998-08-26 |





Description of Item Code

The item code for the Accoat Standard Guide Wire is composed as follows:

- Lunderquist: **PTC-S/Jr-C-F1-0xx-L** (e.g. PTC-S-C-F5-035-L)
- Schüller: **PTC-SCH-S/Jr-C-F1-L1-L2-0xx-L** (e.g. PTC-SCH-S-F5-40-55-035-L)

Each code element is explained in the following table:

| # | Code | Description | # | Code | Description |
|---|------|---------------------------------------------------------------------------------------------------|----|------|-----------------------------------------------------------------------------------------------------------------|
| 1 | PTC | The guide wire is named after the Perkutan Transhepatic Cholangiograph procedure | 6 | F1 | The length of the flexible distal tip in the range from 5 to 20 cm. |
| 2 | SCH | Schüller type | 7 | L1 | The length of the stiff cannula part |
| 3 | S | Straight tip | 8 | L2 | The length of the stiff proximal coil end |
| 4 | Jr | Jr is the shape of the tip in mm. r is the radius of the J tip in the range from 1.5 to 15 mm. | 9 | 0xx | The diameter in inches <ul style="list-style-type: none"> ▪ 025 = 0.025" ▪ 035 = 0.035" |
| 5 | C | PTFE coated | 10 | L | The total length of the guide wire in the range from 50 to 260 cm. |

By inserting values, the item code is transformed into the specific REF number, e.g. PTC-S-C-F5-035-150 for a Lunderquist guide wire with a length of 150 cm.



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