



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 the Medical Device Regulation (Council Regulation 2017/745) may be manufactured and marketed in Denmark/EU and exported without any approval from the Danish Medicines Agency.



Sultan Nur Bayram

Valid from: **01 August 2024**
Valid Until: **01 August 2026**



We have been informed that the products specified below, are manufactured at the site:

SP Medical Sp. Z o.o.
Ul. Ceramiczna 2,
PL-98-220 Zdunska Wola

On behalf of

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

Accoat Standard

Guide Wire

Product list

The following products are covered by EU Certificate HZ 2320977-1.

Item codes – Lunderquist PTC

Item code	Class	Basic UDI-DI	Date for first CE mark
PTC-S-FI-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-Jr-FI-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-S-C-FI-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-Jr-C-FI-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-S-FI-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-Jr-FI-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-S-C-FI-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-Jr-C-FI-035-L	Ila	5710086-GWASKU	1998-08-26

Item codes – Schüller PTC

Item code	Class	Basic UDI-DI	Date for first CE mark
PTC-SCH-S-FI-L1-L2-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-Jr-FI-L1-L2-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-S-C-FI-L1-L2-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-Jr-C-FI-L1-L2-025-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-S-FI-L1-L2-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-Jr-FI-L1-L2-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-S-C-FI-L1-L2-035-L	Ila	5710086-GWASKU	1998-08-26
PTC-SCH-Jr-C-FI-L1-L2-035-L	Ila	5710086-GWASKU	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
PTC	The guide wire is named after the Perkutan Transhepatic Cholangiograph procedure	F1	Length of the flexible distal tip. ▪ 5 – 20 cm.
SCH	Schüller type	L1	Length of the stiff shaft tube part
S	Straight tip	L2	Length of the stiff proximal coil end
Jr	Jr is the shape of the tip in mm. r is the radius of the J tip. ▪ 1.5 - 15 mm.	0xx	The diameter of the guide wire ▪ 025 = 0.025" ▪ 035 = 0.035"
C	PTFE coated	L	Length of the guide wire ▪ 50 - 260 cm.
Without C	Stainless steel		

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.

