



**LÆGEMIDDELSTYRELSEN**

DANISH MEDICINES AGENCY



## Free Sales Certificate

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

**SP Medical A/S  
Møllevvej 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.



Valid from: **19 April 2022**  
Valid Until: **19 April 2024**

*Freja Bauch*  
**Freja Bauch**



# Accoat

## Guide Wire

### Product list

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

#### Item codes – Seldinger Straight

Item code	Class	Basic UDI-DI	Date for first CE mark
S-018-L	III	5710086-GWAC	2012-03-02
S-021-L	III	5710086-GWAC	2012-03-02
S-025-L	III	5710086-GWAC	2012-03-02
S-028-L	III	5710086-GWAC	2012-03-02
S-032-L	III	5710086-GWAC	2012-03-02
S-035-L	III	5710086-GWAC	2012-03-02
S-038-L	III	5710086-GWAC	2012-03-02
S-C-018-L	III	5710086-GWAC	2012-03-02
S-C-021-L	III	5710086-GWAC	2012-03-02
S-C-025-L	III	5710086-GWAC	2012-03-02
S-C-028-L	III	5710086-GWAC	2012-03-02
S-C-032-L	III	5710086-GWAC	2012-03-02
S-C-035-L	III	5710086-GWAC	2012-03-02
S-C-038-L	III	5710086-GWAC	2012-03-02
H-S-018-L	III	5710086-GWAC	2012-03-02
H-S-021-L	III	5710086-GWAC	2012-03-02
H-S-025-L	III	5710086-GWAC	2012-03-02
H-S-028-L	III	5710086-GWAC	2012-03-02
H-S-032-L	III	5710086-GWAC	2012-03-02
H-S-035-L	III	5710086-GWAC	2012-03-02
H-S-038-L	III	5710086-GWAC	2012-03-02
H-S-C-018-L	III	5710086-GWAC	2012-03-02
H-S-C-021-L	III	5710086-GWAC	2012-03-02
H-S-C-025-L	III	5710086-GWAC	2012-03-02
H-S-C-028-L	III	5710086-GWAC	2012-03-02
H-S-C-032-L	III	5710086-GWAC	2012-03-02





Item code	Class	Basic UDI-DI	Date for first CE mark
H-S-C-035-L	III	5710086-GWAC	2012-03-02
H-S-C-038-L	III	5710086-GWAC	2012-03-02
H-X-S-028-L	III	5710086-GWAC	2012-03-02
H-X-S-032-L	III	5710086-GWAC	2012-03-02
H-X-S-035-L	III	5710086-GWAC	2012-03-02
H-X-S-038-L	III	5710086-GWAC	2012-03-02
H-X-S-C-028-L	III	5710086-GWAC	2012-03-02
H-X-S-C-032-L	III	5710086-GWAC	2012-03-02
H-X-S-C-035-L	III	5710086-GWAC	2012-03-02
H-X-S-C-038-L	III	5710086-GWAC	2012-03-02
H-X-X-S-028-L	III	5710086-GWAC	2012-03-02
H-X-X-S-032-L	III	5710086-GWAC	2012-03-02
H-X-X-S-035-L	III	5710086-GWAC	2012-03-02
H-X-X-S-038-L	III	5710086-GWAC	2012-03-02
H-X-X-S-C-028-L	III	5710086-GWAC	2012-03-02
H-X-X-S-C-032-L	III	5710086-GWAC	2012-03-02
H-X-X-S-C-035-L	III	5710086-GWAC	2012-03-02
H-X-X-S-C-038-L	III	5710086-GWAC	2012-03-02

A suffix AAYY can if needed be added at the end of the above listed REF numbers.

#### Item codes – Seldinger J-tip

Item code	Class	Basic UDI-DI	Date for first CE mark
Jr-018-L	III	5710086-GWAC	2012-03-02
Jr-021-L	III	5710086-GWAC	2012-03-02
Jr-025-L	III	5710086-GWAC	2012-03-02
Jr-028-L	III	5710086-GWAC	2012-03-02
Jr-032-L	III	5710086-GWAC	2012-03-02
Jr-035-L	III	5710086-GWAC	2012-03-02
Jr-038-L	III	5710086-GWAC	2012-03-02
Jr-C-018-L	III	5710086-GWAC	2012-03-02
Jr-C-021-L	III	5710086-GWAC	2012-03-02
Jr-C-025-L	III	5710086-GWAC	2012-03-02
Jr-C-028-L	III	5710086-GWAC	2012-03-02
Jr-C-032-L	III	5710086-GWAC	2012-03-02
Jr-C-035-L	III	5710086-GWAC	2012-03-02





Item code	Class	Basic UDI-DI	Date for first CE mark
Jr-C-038-L	III	5710086-GWAC	2012-03-02
H-Jr-018-L	III	5710086-GWAC	2012-03-02
H-Jr-021-L	III	5710086-GWAC	2012-03-02
H-Jr-025-L	III	5710086-GWAC	2012-03-02
H-Jr-028-L	III	5710086-GWAC	2012-03-02
H-Jr-032-L	III	5710086-GWAC	2012-03-02
H-Jr-035-L	III	5710086-GWAC	2012-03-02
H-Jr-038-L	III	5710086-GWAC	2012-03-02
H-Jr-C-018-L	III	5710086-GWAC	2012-03-02
H-Jr-C-021-L	III	5710086-GWAC	2012-03-02
H-Jr-C-025-L	III	5710086-GWAC	2012-03-02
H-Jr-C-028-L	III	5710086-GWAC	2012-03-02
H-Jr-C-032-L	III	5710086-GWAC	2012-03-02
H-Jr-C-035-L	III	5710086-GWAC	2012-03-02
H-Jr-C-038-L	III	5710086-GWAC	2012-03-02
H-X-Jr-028-L	III	5710086-GWAC	2012-03-02
H-X-Jr-032-L	III	5710086-GWAC	2012-03-02
H-X-Jr-035-L	III	5710086-GWAC	2012-03-02
H-X-Jr-038-L	III	5710086-GWAC	2012-03-02
H-X-Jr-C-028-L	III	5710086-GWAC	2012-03-02
H-X-Jr-C-032-L	III	5710086-GWAC	2012-03-02
H-X-Jr-C-035-L	III	5710086-GWAC	2012-03-02
H-X-Jr-C-038-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-028-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-032-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-035-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-038-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-C-028-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-C-032-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-C-035-L	III	5710086-GWAC	2012-03-02
H-X-X-Jr-C-038-L	III	5710086-GWAC	2012-03-02

A suffix AAYY can if needed be added at the end of the above listed REF numbers.





### Item codes – Seldinger Double-ended

Item code	Class	Basic UDI-DI	Date for first CE mark
D-S-Jr-025-L	III	5710086-GWAC	2012-03-02
D-S-Jr-032-L	III	5710086-GWAC	2012-03-02
D-S-Jr-035-L	III	5710086-GWAC	2012-03-02
D-S-Jr-038-L	III	5710086-GWAC	2012-03-02
D-S-Jr-C-025-L	III	5710086-GWAC	2012-03-02
D-S-Jr-C-032-L	III	5710086-GWAC	2012-03-02
D-S-Jr-C-035-L	III	5710086-GWAC	2012-03-02
D-S-Jr-C-038-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-025-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-032-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-035-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-038-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-C-025-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-C-032-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-C-035-L	III	5710086-GWAC	2012-03-02
H-D-S-Jr-C-038-L	III	5710086-GWAC	2012-03-02

A suffix AYYY can if needed be added at the end of the above listed REF numbers.

### Item codes – Seldinger Movable

Item code	Class	Basic UDI-DI	Date for first CE mark
M-S-032-L	III	5710086-GWAC	2012-03-02
M-S-035-L	III	5710086-GWAC	2012-03-02
M-S-038-L	III	5710086-GWAC	2012-03-02
M-S-C-032-L	III	5710086-GWAC	2012-03-02
M-S-C-035-L	III	5710086-GWAC	2012-03-02
M-S-C-038-L	III	5710086-GWAC	2012-03-02
M-Jr-032-L	III	5710086-GWAC	2012-03-02
M-Jr-035-L	III	5710086-GWAC	2012-03-02
M-Jr-038-L	III	5710086-GWAC	2012-03-02
M-Jr-C-032-L	III	5710086-GWAC	2012-03-02
M-Jr-C-035-L	III	5710086-GWAC	2012-03-02
M-Jr-C-038-L	III	5710086-GWAC	2012-03-02
H-M-S-032-L	III	5710086-GWAC	2012-03-02





Item code	Class	Basic UDI-DI	Date for first CE mark
H-M-S-035-L	III	5710086-GWAC	2012-03-02
H-M-S-038-L	III	5710086-GWAC	2012-03-02
H-M-S-C-032-L	III	5710086-GWAC	2012-03-02
H-M-S-C-035-L	III	5710086-GWAC	2012-03-02
H-M-S-C-038-L	III	5710086-GWAC	2012-03-02
H-M-Jr-032-L	III	5710086-GWAC	2012-03-02
H-M-Jr-035-L	III	5710086-GWAC	2012-03-02
H-M-Jr-038-L	III	5710086-GWAC	2012-03-02
H-M-Jr-C-032-L	III	5710086-GWAC	2012-03-02
H-M-Jr-C-035-L	III	5710086-GWAC	2012-03-02
H-M-Jr-C-038-L	III	5710086-GWAC	2012-03-02

A suffix AAYY can if needed be added at the end of the above listed REF numbers.

### Description of Item Code

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

Seldinger subtypes:

**H-X-X-S/Jr-(C)-0xx-L**

Each code element is explained in the following table:

Code	Description	Code	Description
H	Stiff Guide Wire	C	PTFE coated
H-X	Extra Stiff Guide wire	0xx	Diameter of the Guide Wire:
H-X-X	Super Stiff Guide Wire		<ul style="list-style-type: none"> <li>▪ 018 = 0.018"</li> <li>▪ 021 = 0.021"</li> <li>▪ 025 = 0.025"</li> <li>▪ 028 = 0.028"</li> <li>▪ 032 = 0.032"</li> <li>▪ 035 = 0.035"</li> <li>▪ 038 = 0.038"</li> </ul>
S	Straight tip		
Jr	J-tip radius: J1.5 - J15 mm	L	Length of the Guide Wire:
			<ul style="list-style-type: none"> <li>▪ 10 – 450 cm</li> </ul>





Seldinger Double Ended subtypes:

**H-D-S/Jr-(C)-0xx-L**

Each code element is explained in the following table:

Code	Description	Code	Description
H	Stiff Guide Wire	C	PTFE coated
D	Double ended	0xx	Diameter of the Guide Wire: <ul style="list-style-type: none"> <li>025 = 0.025"</li> <li>032 = 0.032"</li> <li>035 = 0.035"</li> <li>038 = 0.038"</li> </ul>
S	Straight tip	L	Length of the Guide Wire: <ul style="list-style-type: none"> <li>30 – 450 cm</li> </ul>
Jr	J-tip radius: J1.5 - J15 mm		

Seldinger Movable subtypes:

**(H)-M-S/Jr-(C)-0xx-L**

Each code element is explained in the following table:

Code	Description	Code	Description
H	Stiff Guide Wire	C	PTFE coated
M	Movable	0xx	Diameter of the Guide Wire: <ul style="list-style-type: none"> <li>032 = 0.032"</li> <li>035 = 0.035"</li> <li>038 = 0.038"</li> </ul>
S	Straight tip	L	Length of the Guide Wire: <ul style="list-style-type: none"> <li>30 – 450 cm</li> </ul>
Jr	J-tip radius: J1.5 - J15 mm		

**Allowed optional variants**

A suffix AYY can if needed be added at the end of the REF numbers:

Purpose, handle national label requirements and identification of different distributors in specific countries.

AA is country abbreviation written with 2 characters.

YY is a number from 01 to 99 in cases where REF number is to identify specific distributors in specific countries.

