



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: **03 March 2022**

Astrid Kolind Christensen



Accoat

Guide Wire

Product list

The following products are covered by EC Certificate 10000457518-PA-NA-DNK.

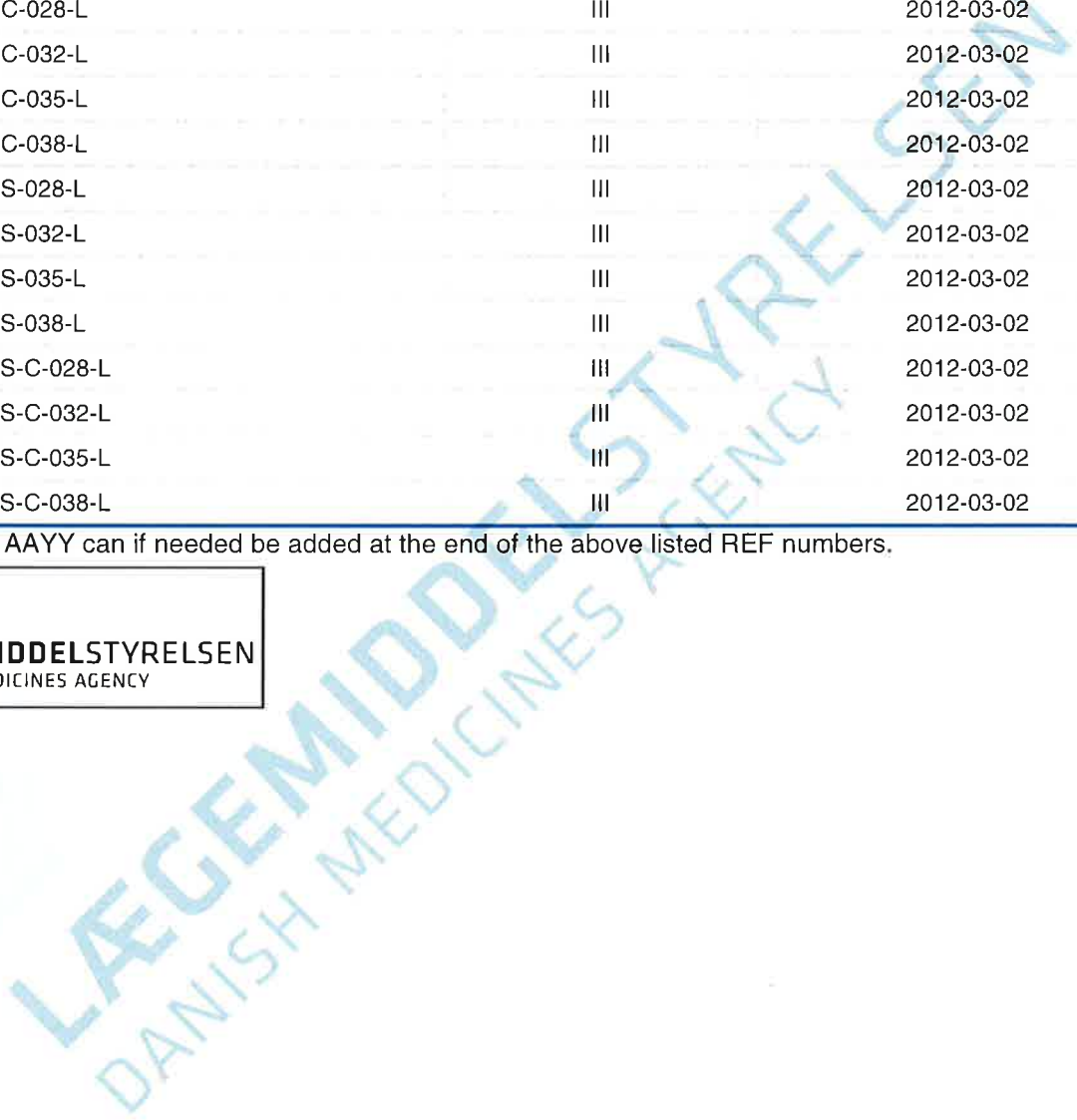
Item codes – Seldinger Straight

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



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





Item code	Class	Date for first CE mark
H-X-Jr-038-L	III	2012-03-02
H-X-Jr-C-028-L	III	2012-03-02
H-X-Jr-C-032-L	III	2012-03-02
H-X-Jr-C-035-L	III	2012-03-02
H-X-Jr-C-038-L	III	2012-03-02
H-X-X-Jr-028-L	III	2012-03-02
H-X-X-Jr-032-L	III	2012-03-02
H-X-X-Jr-035-L	III	2012-03-02
H-X-X-Jr-038-L	III	2012-03-02
H-X-X-Jr-C-028-L	III	2012-03-02
H-X-X-Jr-C-032-L	III	2012-03-02
H-X-X-Jr-C-035-L	III	2012-03-02
H-X-X-Jr-C-038-L	III	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	Date for first CE mark
D-S-Jr-025-L	III	2012-03-02
D-S-Jr-032-L	III	2012-03-02
D-S-Jr-035-L	III	2012-03-02
D-S-Jr-038-L	III	2012-03-02
D-S-Jr-C-025-L	III	2012-03-02
D-S-Jr-C-032-L	III	2012-03-02
D-S-Jr-C-035-L	III	2012-03-02
D-S-Jr-C-038-L	III	2012-03-02
H-D-S-Jr-025-L	III	2012-03-02
H-D-S-Jr-032-L	III	2012-03-02
H-D-S-Jr-035-L	III	2012-03-02
H-D-S-Jr-038-L	III	2012-03-02
H-D-S-Jr-C-025-L	III	2012-03-02
H-D-S-Jr-C-032-L	III	2012-03-02
H-D-S-Jr-C-035-L	III	2012-03-02
H-D-S-Jr-C-038-L	III	2012-03-02

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





Item codes – Seldinger Movable

Item code	Class	Date for first CE mark
M-S-032-L	III	2012-03-02
M-S-035-L	III	2012-03-02
M-S-038-L	III	2012-03-02
M-S-C-032-L	III	2012-03-02
M-S-C-035-L	III	2012-03-02
M-S-C-038-L	III	2012-03-02
M-Jr-032-L	III	2012-03-02
M-Jr-035-L	III	2012-03-02
M-Jr-038-L	III	2012-03-02
M-Jr-C-032-L	III	2012-03-02
M-Jr-C-035-L	III	2012-03-02
M-Jr-C-038-L	III	2012-03-02
H-M-S-032-L	III	2012-03-02
H-M-S-035-L	III	2012-03-02
H-M-S-038-L	III	2012-03-02
H-M-S-C-032-L	III	2012-03-02
H-M-S-C-035-L	III	2012-03-02
H-M-S-C-038-L	III	2012-03-02
H-M-Jr-032-L	III	2012-03-02
H-M-Jr-035-L	III	2012-03-02
H-M-Jr-038-L	III	2012-03-02
H-M-Jr-C-032-L	III	2012-03-02
H-M-Jr-C-035-L	III	2012-03-02
H-M-Jr-C-038-L	III	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: <ul style="list-style-type: none">▪ 018 = 0.018"▪ 021 = 0.021"▪ 025 = 0.025"▪ 028 = 0.028"▪ 032 = 0.032"▪ 035 = 0.035"▪ 038 = 0.038"
H-X-X	Super Stiff Guide Wire		
S	Straight tip		
Jr	J-tip radius: J1.5 - J15 mm	L	Length of the Guide Wire: <ul style="list-style-type: none">▪ 10 – 450 cm



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DANISH MEDICINES AGENCY



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"> ▪ 025 = 0.025" ▪ 032 = 0.032" ▪ 035 = 0.035" ▪ 038 = 0.038"
S	Straight tip	L	Length of the Guide Wire: <ul style="list-style-type: none"> ▪ 30 – 450 cm
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"> ▪ 032 = 0.032" ▪ 035 = 0.035" ▪ 038 = 0.038"
S	Straight tip	L	Length of the Guide Wire: <ul style="list-style-type: none"> ▪ 30 – 450 cm
Jr	J-tip radius: J1.5 - J15 mm		

Allowed optional variants

A suffix AAYY 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.

