



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.



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
Møllevvej 1,
DK-4653 Karise

Accoat

Guide Wire

Product list

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

Item codes – Seldinger Straight

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





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





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





Item code	Class	Basic UDI-DI	Date for first CE mark
H-X-X-Jr-C-028-L	III	5710086-GWACJU	2012-03-02
H-X-X-Jr-C-032-L	III	5710086-GWACJU	2012-03-02
H-X-X-Jr-C-035-L	III	5710086-GWACJU	2012-03-02
H-X-X-Jr-C-038-L	III	5710086-GWACJU	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-GWACJU	2012-03-02
D-S-Jr-032-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-035-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-038-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-C-025-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-C-032-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-C-035-L	III	5710086-GWACJU	2012-03-02
D-S-Jr-C-038-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-025-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-032-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-035-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-038-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-C-025-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-C-032-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-C-035-L	III	5710086-GWACJU	2012-03-02
H-D-S-Jr-C-038-L	III	5710086-GWACJU	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	Basic UDI-DI	Date for first CE mark
M-S-032-L	III	5710086-GWACJU	2012-03-02
M-S-035-L	III	5710086-GWACJU	2012-03-02
M-S-038-L	III	5710086-GWACJU	2012-03-02
M-S-C-032-L	III	5710086-GWACJU	2012-03-02
M-S-C-035-L	III	5710086-GWACJU	2012-03-02
M-S-C-038-L	III	5710086-GWACJU	2012-03-02
M-Jr-032-L	III	5710086-GWACJU	2012-03-02





Item code	Class	Basic UDI-DI	Date for first CE mark
M-Jr-035-L	III	5710086-GWACJU	2012-03-02
M-Jr-038-L	III	5710086-GWACJU	2012-03-02
M-Jr-C-032-L	III	5710086-GWACJU	2012-03-02
M-Jr-C-035-L	III	5710086-GWACJU	2012-03-02
M-Jr-C-038-L	III	5710086-GWACJU	2012-03-02
H-M-S-032-L	III	5710086-GWACJU	2012-03-02
H-M-S-035-L	III	5710086-GWACJU	2012-03-02
H-M-S-038-L	III	5710086-GWACJU	2012-03-02
H-M-S-C-032-L	III	5710086-GWACJU	2012-03-02
H-M-S-C-035-L	III	5710086-GWACJU	2012-03-02
H-M-S-C-038-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-032-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-035-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-038-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-C-032-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-C-035-L	III	5710086-GWACJU	2012-03-02
H-M-Jr-C-038-L	III	5710086-GWACJU	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	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	Extra Stiff Guide wire		
H-X-X	Super Stiff Guide Wire		
S	Straight tip		
Jr	J-tip radius: J1.5 - J15 mm		
C	PTFE coated		
		L	Length of the Guide Wire: <ul style="list-style-type: none"> ▪ 10 – 450 cm





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

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

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.

