



## 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: **10 January 2025**  
Valid Until: **18 November 2026**

*Lise Kristiansen*

**Lise Roving Kristiansen**  
Student Assistant



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**

# Champion

## PTCA Guide Wire

### Product list

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

#### Item codes – Champion PTCA Guide Wire – CTO

Item code	Class	Basic UDI-DI	Date for first CE mark
PTCA-CTO-S-HY-3-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-3-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-S-HY-3-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-3-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-S-HY-6-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-6-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-S-HY-6-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-6-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-S-HY-12-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-12-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-S-HY-12-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CTO-J-HY-12-D-014-300	III	5710086-GWC2J2	2009-04-30

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





**Item codes – Champion PTCA Guide Wire – CAR**

Item code	Class	Basic UDI-DI	Date for first CE mark
PTCA-CAR-S-HY-EF-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-EF-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-EF-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-EF-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-EF-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-EF-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-EF-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-EF-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-F-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-F-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-F-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-F-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-F-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-F-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-F-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-F-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-I-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-I-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-I-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-I-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-I-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-I-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-I-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-I-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-ST-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-ST-D-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-ST-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-ST-D-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-ST-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-ST-H-014-195	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-S-HY-ST-H-014-300	III	5710086-GWC2J2	2009-04-30
PTCA-CAR-J-HY-ST-H-014-300	III	5710086-GWC2J2	2009-04-30

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 Champion PTCA Guide Wire is composed as follows:

Champion PTCA Guide Wire – CTO:

**PTCA-CTO-S/J-HY-Ts-D-014-L**

Champion PTCA Guide Wire - CAR:

**PTCA-CAR-S/J-HY-EF/F//ST-D/H-014-L**

Each code element is explained in the following table:

Code	Description	Code	Description
PTCA	Percutaneous Transluminal Coronary Angioplasty	ST	Tip stiffness standard (Only available for the CAR variant)
CAR	For cardiology use	Ts	CTO tip stiffness. <ul style="list-style-type: none"> <li>▪ 3 gram force</li> <li>▪ 6 gram force</li> <li>▪ 12 gram force</li> </ul>
CTO	For highly stenosed lesions	D	Stent zone stiffness standard
S	Straight tip	H	Stent zone stiffness stiff (Only available for the CAR variant)
J	J-tip	014	Diameter of the guide wire 0.014"
HY	Coil surface hydrophilic coated	L	Length of the Guide Wire. <ul style="list-style-type: none"> <li>▪ 195 cm CAR and CTO</li> <li>▪ 300 cm CAR and CTO</li> </ul>
EF	Tip stiffness extra floppy (Only available for the CAR variant)		
F	Tip stiffness floppy (Only available for the CAR variant)		
I	Tip stiffness intermediate (Only available for the CAR variant)		

### Allowed optional variants

With purpose of handling national label requirements and identification of different distributors in specific countries, a suffix AAYY can, if needed, be added at the end of the REF numbers:

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.

