



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.



Valid from: 21 February 2023
Valid Until: 21 February 2025

Signe Lorentsen
Signe Lorentsen



Champion

PTCA Guide Wire

Product list

The following products are covered by EU Certificate IZ 2320977-3.

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





Item code	Class	Basic UDI-DI	Date for first CE mark
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">▪ 3 gram force▪ 6 gram force▪ 12 gram force
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">▪ 195 cm CAR and CTO▪ 300 cm CAR and CTO
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 AYY 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.

