

**EC Certificate**  
**Design Examination According to**  
**Medical Devices Directive 93/42/EEC Annex-II Section 4**

**Certificate Number: 1984-MDD-21-761**

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

**Organization**

**SP Medical A/S**

Møllevvej 1, 4653 Karise, Denmark

**Product: Champion PTCA Guide Wire**

The products defined at the enclosure which is the part of this certificate and contains two (2) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

**Report Number:** M.6047.01

**Expiry Date:** 27 May 2024



**Muhteşem Gökhan Yücel**  
Head of Notified Body

03 May 2021, Istanbul, Turkey



**Enclosure of the EC Certificate:**

**Design Examination**

**Medical Devices Directive 93/42/EEC Annex-II Section 4**

**Certificate Number: 1984-MDD-21-761**

Concerned medical devices;

**Product: Champion PTCA Guide Wire – CTO**

Ref Number
PTCA-CTO-S-HY-3-D-014-195
PTCA-CTO-J-HY-3-D-014-195
PTCA-CTO-S-HY-3-D-014-300
PTCA-CTO-J-HY-3-D-014-300
PTCA-CTO-S-HY-6-D-014-195
PTCA-CTO-J-HY-6-D-014-195
PTCA-CTO-S-HY-6-D-014-300
PTCA-CTO-J-HY-6-D-014-300
PTCA-CTO-S-HY-12-D-014-195
PTCA-CTO-J-HY-12-D-014-195
PTCA-CTO-S-HY-12-D-014-300
PTCA-CTO-J-HY-12-D-014-300

**Product: Champion PTCA Guide Wire – CAR**

Ref Number
PTCA-CAR-S-HY-EF-D-014-195
PTCA-CAR-J-HY-EF-D-014-195
PTCA-CAR-S-HY-EF-D-014-300
PTCA-CAR-J-HY-EF-D-014-300
PTCA-CAR-S-HY-EF-H-014-195
PTCA-CAR-J-HY-EF-H-014-195
PTCA-CAR-S-HY-EF-H-014-300
PTCA-CAR-J-HY-EF-H-014-300
PTCA-CAR-S-HY-F-D-014-195
PTCA-CAR-J-HY-F-D-014-195
PTCA-CAR-S-HY-F-D-014-300
PTCA-CAR-J-HY-F-D-014-300
PTCA-CAR-S-HY-F-H-014-195

03 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel  
Head of Notified Body



**Enclosure of the EC Certificate:**

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**Design Examination**

**Medical Devices Directive 93/42/EEC Annex-II Section 4**

**Certificate Number: 1984-MDD-21-761**

Concerned medical devices;

**Product: Champion PTCA Guide Wire – CAR**

Ref Number
PTCA-CAR-J-HY-F-H-014-195
PTCA-CAR-S-HY-F-H-014-300
PTCA-CAR-J-HY-F-H-014-300
PTCA-CAR-S-HY-I-D-014-195
PTCA-CAR-J-HY-I-D-014-195
PTCA-CAR-S-HY-I-D-014-300
PTCA-CAR-J-HY-I-D-014-300
PTCA-CAR-S-HY-I-H-014-195
PTCA-CAR-J-HY-I-H-014-195
PTCA-CAR-S-HY-I-H-014-300
PTCA-CAR-J-HY-I-H-014-300
PTCA-CAR-S-HY-ST-D-014-195
PTCA-CAR-J-HY-ST-D-014-195
PTCA-CAR-S-HY-ST-D-014-300
PTCA-CAR-J-HY-ST-D-014-300
PTCA-CAR-S-HY-ST-H-014-195
PTCA-CAR-J-HY-ST-H-014-195
PTCA-CAR-S-HY-ST-H-014-300
PTCA-CAR-J-HY-ST-H-014-300

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



03 May 2021, Istanbul, Turkey

Muhtesem Gökhan Yücel  
Head of Notified Body