CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-760

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

SP Medical A/S

Møllevej 1, 4653 Karise, Denmark

Product: Champion PTCA Guide Wire

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.
Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.6047.01
Expiry Date: 27 May 2024

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

Muhteşem Gökhan Yücel
Head of Notified Body

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