CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-17-463

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:

Wonjin Mulsan Co., Ltd.

89 Geomdan-ro, Seo- gu, Incheon, Korea

Products: Compressible Limb and Circulation Therapy System, Infrared Pain Mitigate Treatment System, Paraffin Bath

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

Report Number: M.4928.01
Expiry Date: 17 October 2022

18 October 2017, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-17-463

Concerned medical devices;

Product: Compressible Limb and Circulation Therapy System
Model Number: POWER-Q1000 PREMIUM, POWER-Q6000, DVT-7700, POWER-Q3000 PLUS, POWER-Q3700, POWER-Q6000 PLUS, PRESS6, WHF-314, POWER-Q1000, PRESS4, WHF-324, POWER-Q1000PLUS, POWER-Q8120, POWER-Q8060, PREMIUM6, POWER-Q6000II, POWER-Q2100, Power-Q2200

Product: Infrared Pain Mitigate Treatment System
Model Number: WHF-312

Product: Paraffin Bath
Model Number: WPB-100, WPB-101, WPB-102, WPB-200, WPB-201, WPB-202, WPB-300, WPB-301, WPB-302

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984

18 October 2017, Istanbul, Turkey

Head of Notified Body

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