Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlin, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 12 0247 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the product - medical device of Class IIa:

Compressible Limb Therapy System

Model: **POWER-Q1000 PREMIUM**

manufactured by company

WONJIN MULSAN Co., Ltd.

Namdong Industrial Complex 10B-7L, 3Fl 623-6 Namchon-dong, Namdong-gu Incheon, Korea

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3 and 5 of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601416/2012, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the **21st March 2017** at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 22nd March 2012

INSTITUTE FOR TESTING AND CERTIFICATION 1023 NOTIFIED BODY

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

WONJIN MULSAN CO.,LTD.

Namdong Industrial Complex 10B-7L,
623-6 Namchon-dong, Namdong-gu, Incheon, Korea

TEL: +82-32-816-0552
FAX: +82-32-816-0557
www.wonjininc.net

24 JAN 2013

Declaration of Conformity

Manufacturer :
Wonjin Mulsan Co., Ltd.
Namdong Industrial Complex 10B-7L,
623-6 Namchon-dong, Namdong-gu, Incheon,
Korea.(Tel : 82-32-816-0552)

Authorized Distributor in Europe :
I.A.C.E.R srl,
Via Sandro Pertini 24/A
30030 Martellago(Venezia)
Italy(Tel : 0039-041-540-1356)

We declare that the Compressible Limb Therapy System(Power-Q 1000 Premium) has been classified as class IIA(according to Annex IX, Rule 9) and is in conformity with the essential requirements and provisions of council Directive 93/42/EEC amended by 2007/47/EC.

The Compressible Limb Therapy System(Power-Q 1000 Premium) is in conformity with the harmonized standards EN 980 : 2008, EN1041: 2008, EN ISO 13485: 2003, EN ISO 14971: 2009, EN ISO 14155-1:2003, IEC 60601-1:88 + A1 : 91 + A2:95, EN 60601-2-10: 1987 + A1 : 2001, EN 60601-1-2 : 2007, EN 60601-1-4 : 1999,EN 60601-1-6, EN ISO 10993-1: 2009.

Is subject to the procedure set out in Annex II(excl. Section 4) of Directive 93/42/EEC amended by 2007/47/EC under the supervision of Notified Body 1023, INSTITUT PRO TESTOVANI A CERTIFIKACI a.s., T. Bati 299, 764 21 ZLIN-LOUKY, Czech Republic

Yours sincerely

Sung-Wook Kim / President
Wonjin Mulsan Co.,Ltd.