



WONJIN MULSAN CO.,LTD.

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

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

## EC Declaration of Conformity

Manufacturer:

**WONJIN MULSAN Co., Ltd.**

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

Tel: +82 32 816 0552 Fax: +82 32 816 0557

**European Representative:**

CMC Medical Devices & Drugs S.L.

C/Horacio Lengo N 18, CP 29006, Málaga, Spain

Tel : +34 951 214 054 / Fax : +34 952 330 100

E-mail : info@cmcmmedicaldevices.com

**Medical device:** Compressible Limb and Circulation Therapy System

-Models: POWER-Q6000PLUS

**Classification :** According to MDD 93/42/EEC and subsequent amendments Annex IX Rule 9, Class IIa

**Conformity assessment route:** Annex II excluding section 4

Wonjin Mulsan Co. Ltd, the undersigned, herewith declarer that the above-mentioned product(s) meet the provisions of the following EC Council Directives and harmonized standards, All Supporting documentations are retained under the premises of the manufacturer and the notified body.

### List of standards

EN ISO 15223-1:2016, EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN 60601-1:2013, EN 60601-1-2:2015, EN 60601-1-6:2015, EN 62304:2006/AC:2008, EN 62366:2008 +A1:2015, MEDDEV 2.7.1 Rev4, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2010

GMDN: 44785

Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.

Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla Istanbul

Country : Turkey

Phone : + 90 216 593 25 75/ Fax : + 90 216 593 25 74

Email : posta@kiwa.com.tr



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Website : [www.kiwa.com.tr](http://www.kiwa.com.tr)  
Notified Body number : 1984

Certificate No.: 1984-MDD-17-463

Expiry date of the Certificate: 17 October 2022

Date CE mark was affixed: 18 October 2017

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Place: Korea

Signature:

Date Jul. 20, 2020

Full Name Kim, Sung wook

Position: President