



WONJIN MULSAN CO.,LTD.

89 Geomdan-ro, Seo-gu,
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EC Declaration of Conformity

Manufacturer:

WONJIN MULSAN Co., Ltd.

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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

-Model: POWER-Q1000PREMIUM

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 60601-1-11:2015, 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 ISO10993-10:2010

GMDN: 44785

Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.

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

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Email : posta@kiwa.com.tr
Website : 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

Place: Korea

Signature:

Date Jul. 20, 2020

Full Name Kim, Sung wook

Position: President