



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@cmcmedicaldevices.com

Medical device: Compressible Limb and Circulation Therapy System

-Models: PRESS 4, PREMIUM 4, and PREMIUM 6

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

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, IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-1-11:2015, MEDDEV 2.7.1 Rev4, EN 62304:2006/AC:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2009 (IEC 60601-1-11:2015 is not applied to PREMIUM 6. EN 62304:2006/AC:2008 is not applied to PRESS 4.)

DIRECTIVES

General applicable directives: EC DIRECTIVE: *Medical Devices Directive*

(MDD 93/42/EEC and subsequent amendments)

Applied harmonized Standards: See TCF- WJ-TCF-01 for PRESS 4, WJ-TCF-03 for PREMIUM 4, and WJ-TCF-16 for PREMIUM 6.

GMDN: 44785

Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.

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

Country : Turkey



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

Phone : + 90 216 593 25 75/ Fax : + 90 216 593 25 74
Email : posta@kiwa.com.tr
Website : www.kiwa.com.tr
Notified Body number : 1984

Conformity assessment route: Annex II 93/42/EEC
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 Jan.28,2020

Full Name Kim, Sung wook

Position: President