



WONJIN MULSAN CO.,LTD.

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

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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

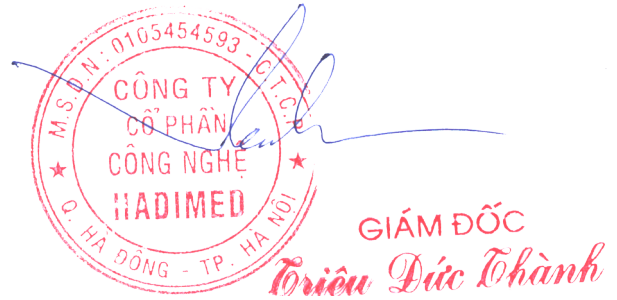
European Representative:

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: Paraffin Bath

Model name: WPB-200

**Classification : According to MDD 93/42/EEC and subsequent amendments Annex IX Rule 9:
Class 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 15223-1:2012, EN 1041:2008, EN ISO 13485:2012, EN ISO 14971:2012, EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-6:2010, MEDDEV 2.7.1 Rev4, EN 62304:2006, EN ISO 10993-1: 2009, EN ISO 10993-5:2009, EN ISO 10993-10:2009

DIRECTIVES

General applicable directives: EC DIRECTIVE: *Medical Devices Directive*
(MDD 93/42/EEC and subsequent amendments)

Applied harmonized Standards: See section TCF- WJ-TCF-16

GMDN: 35147

Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.

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

Country : Turkey

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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:

A handwritten signature in black ink, appearing to read 'Kim, Sung wook'.

Date Jan.24,2019

Full Name Kim, Sung wook

Position: President