

WRP Asia Pacific Sdn Bhd

Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang,

Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486 Facsimile +60-3-8706 1488 Website www.wrpworld.com

Ref No.: WRP/AP/2019/0929

EC DECLARATION OF CONFORMITY

We, WRP Asia Pacific Sdn Bhd, being the manufacturer for the medical devices as described hereafter:

DERMAGRIP-D Dental & Diagnostic Procedure Gloves

Size 5½: D3155-44

Size 6 : D3160-44

Size 6½: D3165-44

Size 7 : D3170-44

Size 7½: D3175-44

Size 8 : D3180-44 Size 8½ : D3185-44

Size 9 : D3190-44

declare under our own responsibility that the above product in Class I medical devices as per Rule 5 of Annex IX is manufactured in conformity with the procedure relating to the EC declaration of conformity set out in Annex VII and meets the essential requirements of Council Directive 93/42/EEC as amended by 2007/47/EC which apply to them under the supervision of the notified body British Standards Institution, and carrying an identification number of 2797.

The product is in conformity with the provisions of Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard No. EN 420:2003 +A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013 and EN ISO 374-5: 2016 is subject to the procedure set out in Module D of Regulation (EU) 2016/425 is identical to the PPE which is the subject of EC certificate of conformity No. CE 688309 issued by BSI (2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

Done at WRP Asia Racific Sdn Bhd, on 19th April 2019.

Dato' Lee Son Hong

Chief Executive Officer/CEO

WRP Asia Pacific Sdn Bhd

Representative Office in the EEA

REMESCO Handelsges.m.b.H

Grinzinger Allee 5/25

A-1190 Vienna

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