WRP Asia Pacific Sdn Bhd
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Selangor Darul Ehsan, Malaysia

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EU DECLARATION OF CONFORMITY

Manufacturers Name:	WRP Asia Pacific Sdn. Bhd.
Manufacturers Address:	Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi, 43900 Sepang, Selangor Darul Ehsan, MALAYSIA
Authorized Representative Name:	REMESCO Handelsges.m.b.H
Authorized Representative Address:	Muthgasse 36/19, A- 1190 Vienna, Austria
SRN (Single Registration Number):	MY-MF-000004690
Basic UDI-DI:	9557795LTX-EG01N8
Name of the Device (s):	DERMAGRIP D-Dental & Diagnostic Procedure Gloves
Product code:	5 ½: D3155-44 7 ½: D3175-44 6.0: D3160-44 8.0: D3180-44 6 ½: D3165-44 8 ½: D3185-44 7.0: D3170-44
Intended Use:	To prevent contamination between healthcare personnel and the patients body, fluids, waste or environment. They are not intended for surgical work.
Classification:	Class I - Non-sterile (As per rule 5 of Annex VIII) Category III
Conformity assessment route:	WRP Asia Pacific Sdn. Bhd uses the following procedures for the CE-labeling of our products according the Regulation (EU) MDR 2017/745: Class I (Non-sterile): EU conformity assessment according to Annex II and Annex III.

This declaration of conformity is issued under the sole responsibility of WRP Asia Pacific Sdn. Bhd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices and fulfil the requirements of EN 455-1:2020, EN 455-2: 2015, EN 455-3:2015, EN 455-4:2009. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI (2797), Say Building, John M. Keynesplein 9, 11066 EP, Amsterdam, The Netherlands, Certificate no. MD 99288. All supporting documentation is retained at the premises of the manufacturer.

The product is also 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 EU certificate of conformity No. CE 688306 issued by BSI (2797), Say Building, John M. Keynesplein 9, 11066 EP, Amsterdam, The Netherlands.

Done at WRP Asia Pacific Sdn Bhd, on 22/9/2021.

Signature .....

(Goh Bee Hong)
President
WRP Asia Pacific Sdn Bhd