WRP Asia Pacific Sdn Bhd
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Ref No.: WRP/AP/2019/0997

EC DECLARATION OF CONFORMITY

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

COMFIT Premium POWDERED LATEX SURGICAL GLOVES

Size 5½ : C3055-05
Size 6 : C3060-05
Size 6½ : C3065-05
Size 7 : C3070-05
Size 7½ : C3075-05
Size 8 : C3080-05
Size 8½ : C3085-05
Size 9 : C3090-05

declare under our own responsibility that the above product in Class IIa medical devices as per Rule 7 of Annex IX is manufactured in conformity with the procedure relating to the EC declaration of conformity set out in Annex II (Full quality assurance audit by a notified body to BS EN ISO 13485), excluding Section 4, 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 and certified in EC Certificate No. CE 00742 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 688313 issued by BSI (2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

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

Dato' Lee Son Hong
Chief Executive Officer/CEO
WRP Asia Pacific Sdn Bhd

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