



**WRP Asia Pacific Sdn Bhd**

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## EC DECLARATION OF CONFORMITY

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

### **Radiaxon Polyisoprene Powder Free Radiation Attenuating Surgical Gloves, Sterile**

**Size 6 : R3560-85**

**Size 6 ½: R3565-85**

**Size 7: R3570-85**

**Size 7 ½: R3575-85**

**Size 8 : R3580-85**

**Size 8 ½: R3585-85**

**Size 9: R3590-85**

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 VII and meets the essential requirements set out in Annex I 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 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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 and EN ISO 374-5:2016, is subject to the procedure set out in Module D of Regulation (EU) 2016/425 and is identical to the PPE which is the subject of EC certificate of conformity No. CE 724079 issued by BSI (2797), Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

Done at WRP Asia Pacific Sdn Bhd, on 4<sup>th</sup> December 2020.

  
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Leong Wai Leong  
President  
WRP Asia Pacific Sdn Bhd

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