



WRP Asia Pacific Sdn Bhd
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EC 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: REMESCO Handelsges.m.b.H

Authorized Representative Address: Muthgasse 36/19, A- 1190 Vienna, Austria

Name of the Device (s): Radiaxon Natural Rubber Latex Radiation Attenuating Surgical
Glove, Sterile

Product code: R32XX28

Classification: Class IIa - Sterile (As per rule 7 of Annex IX)
Category III - Complex PPE

Notified Body name: British Standards Institution (BSI)

Notified Body Address: Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam,
Netherlands.

Conformity assessment route: WRP Asia Pacific uses the following procedures for the CE-labeling of
our products according to European Medical Device Directive
93/42/EEC:


Class IIa: EC conformity assessment according to Annex II, excluding
Section 4.

This declaration of conformity is issued under the sole responsibility of WRP Asia Pacific. We hereby declare that the medical device(s) specified above meet the provision of European Medical Device Directive 93/42/EEC for medical devices and fulfil the requirements of EN 455-1, 2, 3 and 4. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI, 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. No. EN 61331-1:2014, EN 61331-3:2014, EN 21420:2020, EN ISO 374-1:2016+A1:2018, EN 374-2:2019, EN 16523-1:2015, EN 374-4:2019 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 724056 issued by BSI.

Done at WRP Asia Pacific Sdn Bhd, on 12.10.2022.

Signature:


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(Goh Bee Hong)
President
WRP Asia Pacific Sdn Bhd



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