WRP Asia Pacific Sdn Bhd
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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
Manufacturer SRN (Single Registration Number):	MY-MF-000004690
Authorized Representative Name:	REMESCO Handelsges.m.b.H
Authorized Representative Address:	Muthgasse 36/19, A- 1190 Vienna, Austria
Authorized Representative (Single Registration Number):	AT-AR-00002669
Basic UDI-DI:	9557795RPG-SG01KT
Name of the Device (s):	Radiaxon Powder Free Latex Radiation Attenuating Surgical Gloves, Sterile
Product code:	R32xx-28
Intended Use:	These gloves are intended to be used during surgical works, short term and single use only. This surgical glove acts as protective barrier when worn on the hand of surgeon and healthcare personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste or environment against dangerous chemicals and micro-organisms. It also provide protection against scattered secondary radiation exposure originating from X-ray beam.
Classification:	Class IIa (As per rule 7 of Annex VIII) Category III – Complex PPE, Regulation (EU) 2016/425
Notified Body Name:	BSI Group the Netherlands B.V (2797)
Notified Body Address:	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: The Regulation (EU) MDR 2017/745; Class IIa: EU conformity assessment according to Annex IX PPE Cat. III, according to Annex VIII (Module D) of PPE Regulation 2016/425, certified under CE 688305

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 provisions of Regulation (EU) 2017/745 [MDR 740797] 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 European consensus 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 in accordance with ISO 16604:2004. BSI (British Standard Institution) with address BSI Group The Netherlands B.V, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands (2797), performed the EU type examination (Module B) and issued the EU type-examination certificate of conformity No. CE 724056.

Done at WRP Asia Pacific Sdn Bhd, on [04.12.2023].

Signature:

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(Goh Bee Hong)
President
WRP Asia Pacific Sdn Bhd

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