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):	Profeel DHD Polyisoprene Sensitive Powder Free, Surgical Glove, Sterile
Product code:	P33XX-57
Classification:	Class IIa - Sterile (As per rule 7 of Annex IX) Category III - Complex PPE, Regulation (EU) 2016/425
Notified Body name:	British Standards Institution (BSI)
Notified Body Address:	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The 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 (Sterile): EC conformity assessment according to Annex II excluding section 4. 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. 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. 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 performed the EU type examination (Module B) and issued the EU type-examination certificate of conformity No. [CE 688311].

Done at WRP Asia Pacific Sdn Bhd, on 26/4/2023.
Signature:

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(Goh Bee Hong)
President
WRP Asia Pacific Sdn Bhd

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