WRP Asia Pacific Sdn Bhd
147817V
Lot 1, Jalan 3, Kawasan Perusahaan
Bandar Baru Salak Tinggi,
43900 Sepang,
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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:	9557795NBR-EG02BG
Name of the Device (s):	*Refer Attachment 1*
Product code:	*Refer Attachment 1*
Intended Use:	To prevent contamination between healthcare personnel and the patients body, fluids, waste or environment. They are not intended for surgical work.
Classification:	Class Is - Sterile (As per rule 5 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 Is (Sterile): 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 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 688314.

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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ATTACHMENT I: NAME OF THE DEVICE & PRODUCT CODE

No.	Name of the Devices	Product Code
1.	Dermagrip Ultra Nitrile Examination Gloves, Powder Free, Sterile	D15xx-82
2.	Dermagrip Extended Cuff Nitrile Examination Gloves, Powder Free, Sterile	D14xx-43