



**WRP Asia Pacific Sdn Bhd**

147817V

Lot 1, Jalan 3, Kawasan Perusahaan Bandar Baru Salak Tinggi,  
Bandar Baru Salak Tinggi,  
43900 Sepang,  
Selangor Darul Ehsan, MALAYSIA

Office +60-3-8706 1486

Facsimile +60-3-8706 1488

Website www.wrpworld.com

## 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:** 9557795LTX-EG01N8

**Name of the Device (s):** Refer Attachment 1

**Product code:** Refer Attachment 1

**Intended Use:** These gloves are intended for single use only and acts as protective barrier when worn by healthcare personnel to prevent contamination between healthcare personnel and patient's body, fluids, waste, or environment against dangerous chemicals and micro-organisms.

**Classification:** Class I - Non-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 I (Non-sterile); EU conformity assessment according to Annex IV, certified by self-declaration.

PPE Cat. III, according to Annex VIII (Module D) of PPE Regulation 2016/425, certified under CE 688305

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth/Death Certificate is that of **Lee Moi Yin** who is ..... from Notary Public. The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.



**Mohamad Nizam Ramli**  
Consular Officer  
Consular Division  
Ministry of Foreign Affairs  
Putrajaya Malaysia

21 JAN 2025

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 688306.

Done at WRP Asia Pacific Sdn Bhd, on [28.11.2024].

Signature:

(Goh Bee Hong)  
President  
WRP Asia Pacific Sdn Bhd



**LEE MOI YIN**  
NOTARY PUBLIC  
PETALING JAYA  
SELANGOR  
MALAYSIA



T.C.  
KUALA LUMPUR BÜYÜKELÇİLİĞİ  
KONSOLOSLUK ŞUBESİ  
Bu belge çerinde ver alan imza ve mührün  
Malezya İşleri Bakanlığı'na ait olduđu  
onaylanır. İşbu onay metne şamil deđildir.  
Tarife : 5/III/3a  
Harç : RM85  
Makbuz : 38391616 No : 229



13 Şubat 2025



**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 Classic NR Latex Powder Free Examination Gloves, Non-Sterile	D15xx-10
2.	Dermagrip Ultra Latex Powder Free Examination Glove, Non-Sterile	D10xx-20
3.	Dermagrip Latex Powder Free Examination Glove, Non-Sterile	D15xx-30
4.	Dermagrip Polymer Coated NR Latex Powder Free Examination Gloves, Non-Sterile	D14xx-45
5.	Dermagrip Coated LS NR Latex Powder Free Examination Gloves, Non-Sterile	D11xx-31
6.	Safedon Dermagrip NR Latex Powder Free Examination Gloves, Non-Sterile	D15xx-50
7.	Dermagrip Extra NR Latex Powder Free Examination Gloves, Non-Sterile	D14xx-04
8.	Dermagrip-D Dental & Diagnostic Procedure NR Latex Powder Free Examination Gloves, Non-Sterile	D31xx-44



