



WRP Asia Pacific Sdn Bhd

1 4 7 8 1 7 V

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

Office +60-3-8706 1486

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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-SG01RA

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

Product code: *Refer Attachment I*

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.

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 688309.

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.	PROFEEL Power Free Natural Rubber Latex Surgical Gloves, Sterile	P33xx-21
2.	PROFEEL DHD Platinum Power Free Natural Rubber Latex Surgical Gloves, Sterile	P33xx-01
3.	PROFEEL DHD Micro Power Free Natural Rubber Latex Surgical Gloves, Sterile	P33xx-34
4.	PROFEEL DHD Extra Protection Power Free Natural Rubber Latex Surgical Gloves, Sterile	P33xx-35
5.	PROFEEL DHD Sensitive Power Free Natural Rubber Latex Surgical Gloves, Sterile	P33xx-55
6.	PROFEEL Double Gloving System Powder Free Natural Rubber Latex Surgical Overglove and Underglove, Sterile	P33xx-61
7.	COMFIT PREMIUM Powder Free Natural Rubber Latex Surgical Gloves, Sterile	C36xx-96
8.	COMFIT Powder Free Natural Rubber Latex Surgical Gloves, Sterile	C40xx-93
9.	EPIC MT Powder Free Natural Rubber Latex Surgical Gloves, Sterile	EP-12-xx



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