



STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn. Bhd.

Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 ¾, Jalan Kapar,
42100 Klang,
Selangor Darul Ehsan, Malaysia.

Under the sole responsibility as a manufacturer, declare that the following product described hereafter:

POWDER FREE NITRILE EXAMINATION GLOVES BLUE, WHITE AND BLACK COLORED, NON-STERILE, LOW DERMATITIS POTENTIAL

Basic UDI-DI: 955 525660 NE PF D LA

is in conformity with the

- 1) **Medical Device Regulation (EU) 2017/745**, under Class I Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009. It is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

And

- 2) **Personal Protective Equipment Regulation (EU) 2016/425**, under Category III risk per set out in Annex I, complying with the European standards EN 420:2003+A1:2009, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016. It is identical to the PPE which is subject to the EU Type Examination (Module B) under certificate number **2777/10013-04/E00-00** issued by Notified Body:

SATRA Technology Europe Limited (2777)


Bracetown Business Park, Clonee, Dublin 15, D15 YN2P, Ireland

and is subject to the annual conformity assessment procedure which is based on the quality assurance of the production process (Module D) under surveillance of the Notified Body:

BSI Group The Netherlands B.V. (2797)

Say Building, John M. Keynesplein 9, 1066 EP Amsterdam,
The Netherlands.

The above-mentioned product demonstrates fulfilment to the essential health and safety requirements set out in Annex II of PPE Regulation (EU) 2016/425.

Signature : 
 Name : Cho Sow Fong
 Position : Senior Manager, Regulatory Affairs
 Date : 15 April 2021
 Signed and on behalf of: Kossan International Sdn. Bhd.

Selangor, Malaysia

Issue Place

Stamp:

KOSSAN INTERNATIONAL SDN. BHD. (278178-M)

Wisma KOSSAN, Lot 782, Jalan Sungai Putus,
Off Batu 3¾, Jalan Kapar, 42100 Klang,
Selangor, Malaysia.

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