



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 LATEX EXAMINATION GLOVES NATURAL COLORED, NON-STERILE

Basic UDI-DI: 955 525660 NE PF L LS

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 **2777/11630-01/E00-00** issued by Notified Body:

SATRA Technology Europe Limited (2777)


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

and is subject to the annual conformity assessment procedure which is based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified Body:

SATRA Technology Europe Limited (2777)

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

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. (273178-M)

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