



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.

with his EU representative, established in the European Community:

Obelis s.a.
Corporate Office:
Bd. Général Wahis 53...
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03

Is issuing this EU Declaration of Conformity under the sole responsibility of the manufacturer, declaring 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 455-1:2020, 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 (product reference **PFN LD**) 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



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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 : 30 June 2021
Signed and on behalf of: Kossan International Sdn. Bhd.

Selangor, Malaysia

Issue Place

Stamp:

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

Wisma KOSSAN, Lot 782, Jalan Sungai Putus,
Off Batu 3¼, Jalan Kapar, 42100 Klang,
Selangor, Malaysia.

T : +603 3291 2657 F : +603 3291 0584