

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn. Bhd.

KOSSAN Tower,

No. 6D, Persiaran Setia Dagang,

Setia Alam, Seksyen U13

40170 Shah Alam, Selangor, Malaysia

Manufacturer SRN: MY-MF-000022331

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 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, 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.

The following quality management system standard requirement are used to demonstrate fulfilment to the General Safety and Performance Requirements set out in Annex I of the MDR Regulation (EU) 2017/745.

**ISO 9001:2015
EN ISO 13485:2016**

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 ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN 421:2020. It is identical to the PPE (product reference **PFN LD**) which is subject to the EU Type Examination (Module B) under certificate number **2777/10013-06/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) 2016/42

Signature : 
 Name : Cho Sow Fong
 Position : Assistant General Manager,
 Regulatory Affairs

Date : 14 Feb 2025

Signed and on behalf of: Kossan International Sdn. Bhd.

Selangor, Malaysia

Issue Place
Stamp:

