# 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

with his EU representative, established in the European Community:

**Advena Limited**
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advena.mt
SRN*: MT-AR-000000234*

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

**POWDER FREE NITRILE EXAMINATION GLOVES**
**BLUE, WHITE, BLACK AND PINK 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.

   The products are intended to be worn on the examiner's hand for medical purposes to provide a barrier against potentially infections materials and other contaminants.



**KOSSAN INTERNATIONAL SDN. BHD.** 199301018440 (273178-M)
*(A subsidiary of Kossan Rubber Industries Bhd.)*
KOSSAN Tower, No. 6D, Persiaran Setia Dagang, Setia Alam, Seksyen U13, 40170 Shah Alam, Selangor, Malaysia.
**T** +603-5626 0888 **F** +603-5870 4294 **E** kossan@kossan.com.my **www.kossan.com.my**

The following quality management system standard requirements 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 I risk per set out in Annex I, complying with the European standards EN ISO 21420:2020+A1:2024.

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 : Assistant General Manager, Regulatory Affairs
Date : 20 August 2026

***Selangor, Malaysia***
Issue Place

Stamp:

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



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# UK DECLARATION OF CONFORMITY

We,

**Kossan International Sdn Bhd**
KOSSAN Tower,
No. 6D, Persiaran Setia Dagang,
Setia Alam, Seksyen U13
40170 Shah Alam, Selangor, Malaysia

with his Responsible Person, established in the United Kingdom:

**Advena Ltd UK**
Pure Offices, Plato Close
Tachbrook Park
Warwick CV34 6WE
United Kingdom
E-mail: info@advenamedical.com

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

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

**Basic UDI-DI: 955 525660 NE PF D LA**

is in conformity with the

1) **Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)**, under Class IIa Medical Device per set out in Rule 6 and Rule 7 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC. The device also complies with the Designated standards BS EN 455-1:2020+A2:2024, BS EN 455-2:2024, BS EN 455-3:2023, and BS EN 455-4:2009.

   The following quality management system standard requirements are used to demonstrate fulfilment to the essential requirements of the above directive:

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

And



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2) **Personal Protective Equipment Regulation (EU) 2016/425 as retained in UK Law and amended**, under Category I risk per set out in Annex I, complying with the Designated Standards BS EN ISO 21420:2020+A1:2024

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

Signature : 
Name : Cho Sow Fong
Position : Assistant General Manager, Regulatory Affairs
Date : 20 August 2026

***Selangor, Malaysia***
Issue Place

Stamp:


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



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