



STRETCHING LIMITS • SINCE 1979

**KOSSAN INTERNATIONAL SDN. BHD.** 199301018440 (273178-M)

## EU DECLARATION OF CONFORMITY

We,

**Kossan International Sdn Bhd**  
Wisma Kossan, Lot 782, Jalan Sungai Putus,  
Off Batu 3 3/4, Jalan Kapar,  
42100 Klang, Selangor, Malaysia.  
SRN: MY-MF-000022331

with his EU representative, established in the European Community:

**Advena Limited**  
Tower Business Centre  
2<sup>nd</sup> 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:

| Product Description  | Size            | Brand               |
|--|-----------------|---------------------|
| Sterile Powder Free Nitrile Examination Gloves, Blue Color | XS, S, M, L, XL | iNtouch V Synthetic |
| Basic UDI-DI:<br>955 525660 SEPFN NM                       |                 |                     |

is in conformity with the

**Medical Device Regulation (EU) 2017/745**, under Class Is Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

Conformity assessment was performed according to Article 52 (7), per set out in Part A of Annex XI of the regulations, under certificate number 742058 R000.

The conformity assessment is carried out by:

**BSI Group The Netherlands B.V. (2797)**  
Say Building,  
John M. Keynesplein 9,  
1066 EP Amsterdam,  
The Netherlands.



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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**

Signature:

**Selangor, Malaysia**

Issue Place

Stamp:



Name : Cho Sow Fong  
Position : Senior Manager, Regulatory Affairs  
Date : 03 June 2022

Signed and on behalf of: Kossan International Sdn. Bhd