KOSSAN

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
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advema.mt
SRN*: MT-AR-000000234*

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

Product Description/ Basic UDI-DI	Size	Brand
Sterile Powder Free Latex Surgical Gloves Blue, Brown and Natural Colored Basic UDI-DI: 955 525660 SSPFL RK	5½, 6, 6½, 7, 7½, 8, 8½, 9	iNtouch Powder Free

is in conformity with the

1) **Medical Device Regulation (EU) 2017/745**, under Class IIa Medical Device per set out in Rule 6 and Rule 7 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 (6), per set out in Section 10 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.

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

is in conformity with the

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. It is identical to the PPE (product reference **Sterile Powder Free Latex Surgical Gloves (iNtouch)**) which is subject to the EU Type Examination (Module B) under certificate number **CE 692798** issued by Notified Body:

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

and is subject to the annual conformity assessment procedure which is based on 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:

Selangor, Malaysia
Issue Place
Stamp:

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

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

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