



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/Basic UDI-DI	Size	Brand
Sterile Powdered Latex Surgical Gloves	5½, 6, 6½, 7, 7½, 8, 8½, 9	iNtouch Powdered
Basic UDI-DI: 955 525660 SSPPL SH		

is in conformity with the **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.



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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:

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

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

**Selangor, Malaysia**

Issue Place

Stamp:

