



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

STRETCHING LIMITS • SINCE 1979

## EC-DECLARATION OF CONFORMITY

The manufacturer:

**Kossan International Sdn Bhd**  
Wisma Kossan, Lot 782, Jalan Sungai Putus,  
Off Batu 3 3/4, Jalan Kapar,  
42100 Klang, Selangor, Malaysia.

with his EU representative, established in the European Community:

**Obelis s.a.**

**Corporate Office:**  
Bd. Général Wahis 53,  
B-1030 Brussels, Belgium.  
Tel: +3227325954  
Fax: +3227326003

**Registered address:**

Avenue de Tervuren, 34, Box 44  
B-1040 Brussels, Belgium

declare that the MDD described hereafter:

### **Sterile Powder Free Latex Surgical Gloves (iNtouch Slide)**

under Class IIa Medical Device per 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.

Conformity assessment was performed according to Article 11 (5), Annex VII, Section 3 and Annex V, Section 3.2 of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

The conformity assessment is carried out by:

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

The following standards are used to prove the products conformity with the essential requirements of the above directive:

ISO 9001:2015  
ISO 13485:2016 & EN ISO 13485:2016

Signature:

Name: Ms. Cho Sow Fong  
Designation: Manager of Regulatory Affairs  
Date: 1 April 2019

Issue Place: Selangor, Malaysia  
Company stamp:

**KOSSAN INTERNATIONAL SDN. BHD.** (273178-M)  
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Selangor, Malaysia.  
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