KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

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 Spot)

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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