

DECLARATION OF CONFORMITY

I, Ang Teck Leong, hereby declare that the below mentioned medical device—

- (i) complies with all the requirements under the Act;
- (ii) has been classified according to the classification rules as specified in First Schedule on Rules of Classification of Medical Device; and
- (iii) conforms to requirements specified in APPENDIX 1 of Third Schedule on Essential Principles for Safety and Performance of Medical Devices under Medical Devices Regulations 2012.

(A) Particulars of medical device

Generic name : Non-Sterile Natural Rubber Latex Examination Glove,
Pre-powdered/Powder-Free
Specified name : Latex Examination Gloves
Brand/model : Kleenhands, Hanser
Manufacturer : SSN Medical Products Sdn Bhd
Country of origin : Malaysia
Manufacturing site : Lot 31793, Jalan KPB 12, Kampung Baru Balakong,
43300 Selangor Darul Ehsan, Malaysia
Risk-based classification : MDA - Class A (Low risk)
US FDA - Class I (Low risk)
Classification rule : Rule 5 (According to First Schedule on Rules of
Classification of Medical Device)

Medical device registration number/approval code:
MDA - GMD27352389217A, GMD35761946019A
US FDA 510 (k) - K990527, K990526

(B) Quality Management System certificate (“QMS”)

Conformity Assessment Body issuing the certificate: SIRIM QAS International
Certificate number : QMS-MD 00178
Issuance date : 25 February 2021
Expiry date : 24 February 2024

(C) Standards Applied

Standards applicable for the above-mentioned medical device:
ISO 13485:2016, ASTM D3578-19, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015,
EN 455-4:2009, BS EN ISO 14971:2019, EN ISO 374-1:2016, EN ISO 374-2:2019,
EN 16523-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 30th April 2021.

I fully understand and acknowledge that it is an offence under Section 76 of the Medical Device Act 2012 [Act 737] to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:



Ang Teck Leong

30th April 2021

Date