MAXTER
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

LOT 6070
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: info@maxter.com.my

Date: 21st December 2020

To Whom It May Concern

EU DECLARATION OF CONFORMITY

We, MAXTER GLOVE MANUFACTURING SDN. BHD. located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles off Jalan Meru, 41050 Klang, declares that the medical devices described hereafter as:-

- ñ**Superguard**ò label, Non Sterile 2.2Mil Purple Blue Powder Free Nitrile Examination Gloves
  UDI-DI code: 9-555002-114497, 9-555002-114503 and 9-555002-114510

- Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices.

- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745.

- Are in conformity with the national standard transposing harmonized standard EN 455-1, EN 455-2, EN 455-3 and EN455-4.

- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS UK Ltd System & Services Certification, Rossmore Business Park Ellesmere Port Cheshire CH653EN, United Kingdom.

- Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager