

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: maxter@tm.net.my www.maxter.com.my

Date: 10<sup>th</sup> June 2024

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, Selangor, Malaysia declares under our sole responsibility that the devices described hereafter as:

"FLOWER SMART" label, Non-Sterile Powder Free Latex Examination Gloves Product reference: MTCLPF

-are PPE Category III covered by EU Type Examination Certificate No: 2777/12719-04/E00-00

are in conformity with:

- The provisions of Regulation (EU) 2016/425 and the requirements of the European harmonized standard EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 and EN ISO 374-5:2016 and it is subject to the EU Type Examination (Module B) by Notified Body: SATRA (2777)
  Bracetown Business Park, Clonee D15YN2P, Republic of Ireland.
- Is subject to the conformity assessment procedure set out in Module D of Regulation (EU) 2016/425 under surveillance of the Notified Body: SGS FIMKO OY (0598) Takomotie 8, FI-00380 Helsinki, Finland.
- The gloves are manufactured according to ISO 9001:2015 and 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 European authorised representative is Obelis S.A., Bd. General Wahis 53, 1030 Brussels, Belgium.

Maxter Glove Manufacturing Sdn Bhd

Signed for and on behalf of

Klang, Selangor Malaysia Yap Peak Geeh QA & Regulatory Affairs Senior Manager