M A X T E R
GLOVE MANUFACTURING SDN BHD
(229862-H)
since 1989

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru
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1st September 2021

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 medical devices and PPE described hereafter as:-

- **"MAXTER" label, Non Sterile 2.2mil Cobalt Blue Powder Free Nitrile Examination Gloves**
  Basic UDI-DI: **955 500211 638CT**
  Product Reference: **PFSN-FTCB**
  Article No.: **MX93775, MX93776, MX93777, MX93778, MX93779**

are in conformity with:-

- The general safety and performance requirements of Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of the Medical Device Regulation (EU) 2017/745
- With the national standard transposing harmonized standard EN455-1, EN455-2, EN455-3 and EN455-4 and is self-certified as a Class I non-sterile medical device.
- The provisions of Personal Protective Equipment (PPE) – Regulation (EU) 2016/425 and the requirements of the European harmonized standard EN420:2003+A1:2009, EN ISO 374-1:2016, and EN ISO 374-5:2016, EN 374-2:2014, EN 16523-1:2015 and EN 374-4:2013.
- Is identical to the PPE which is subject to the EU Type Examination Certificate (Module B), certificate no.: 2777/12706-01/E00-00 issued by the Notified Body:
  SATRA (2777)
  Bracetown Business Park, Clonee D15YN2P, Republic of Ireland.
- Is subject to the procedure set out in Module D of regulation (EU) 2016/425 as a Category III product and under the supervision of the Notified Body:
  SGS FIMKO OY (0598)
  P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland.
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
- Our Authorized EU 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