MAXWELL
GLOVE MANUFACTURING BERHAD
(99472-X)
since 1989

Plot 116 &117, Jalan Logam 7
Kws Perindustrian Kamunting Raya 3
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10th June 2019

To Whom It May Concern:

EC DECLARATION OF CONFORMITY

We, **MAXWELL GLOVE MANUFACTURING SDN. BHD., located at Plot 116 & 117, Jalan Logam 7, Kawasan Perindustrian Kamunting Raya 3, 34600 Kamunting,** declare that the devices manufactured by us,

- **Non Sterile Powder Free Nitrile Examination Gloves, 4.5mil, Colour: Regular Blue, Product Reference: PFTN-FTRB & PFTN-PTRB**
- **Non Sterile Powder Free Nitrile Examination Glove with Long Cuff, Product Reference: PFLN-PTRB**
- **Non Sterile Powder Free Nitrile Examination Glove, 5.0mil, Colour: Bluple and Black, Product Reference: PFHN-FTBP, PFHN-FTBK & PFHN-PTBK**

to which this declaration relates are in conformity with:-

- The provisions of Regulation (EU) 2016/425 and, the requirements of the European harmonized standard EN420:2003+A1:2009 and EN374-1:2016, and it is identical to the PPE which is subject to the EU Type Examination Certificate (Module B), certificate no.: 2777/12717-01/E00-00 and 2777/12712-01/E00-00 issued by the 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 the surveillance of the Notified Body:
  SGS FIMKO OY (0598)
  P.O. Box 30 (Sarkiniementie 3), 00211 Helsinki, Finland.

- The gloves are manufactured according to ISO 9001:2015 ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS, UK Limited.

- Our European Representative is Supermax Healthcare Limited, 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.

Kamunting, Perak
Malaysia

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Tan Bow Kok
General Manager- Manufacturing