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

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru
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10th 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 medical devices described hereafter as:

- **"FLOWER SMART"** label, Non-Sterile Powder Free Latex Examination Gloves
  Basic UDI-DI: **955 500211 637CR**

  Single Registration Number (SRN): **MY-MF-000016719**

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 the Medical Device Regulation (EU) 2017/745
- The EU Declaration of Conformity is assured according to the guidelines set out in Annex IV Medical Device Regulation (EU) 2017/745
- The national standard transposing harmonized standard EN455-1, EN455-2, EN455-3 and EN455-4
- 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 European authorised representative is Obelis S.A., Bd. General Wahis 53, 1030 Brussels, Belgium

Signed for and on behalf of
Maxter Glove Manufacturing Sdn Bhd

Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Senior Manager