



SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)

Lot 38, Putra Industrial Park, Bukit Rahman Putra
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Date: 27 July 2021

To Whom It May Concern

EU DECLARATION OF CONFORMITY

We, **SUPERMAX GLOVE MANUFACTURING SDN. BHD.** A registered manufacturer and exporter of disposable medical examination and surgical gloves located at Lot 38, Putra Industrial Park, Bukit Rahman Putra 47000 Sungai Buloh, declares that the medical devices described hereafter as :-

- **“MEDIC-DENT” Label, Non Sterile Powder Free Latex Examination Gloves**
Basic UDI-DI: 955 100345 123 B3
- 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 United Kingdom Ltd Systems & Services Certification.
- Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.
- The technical file “DOCUMENT NO.: SGM-FTF-2B” dated 9th January 2020 contains all the relevant technical information.

**Sungai Buloh, Selangor
Malaysia**



Yap Peak Geeh
QA & Regulatory Affairs Manager