

Certificate MY00/51449

The management system of

# Supermax Glove Manufacturing Sdn. Bhd.

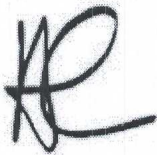
Lot 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia

has been assessed and certified as meeting the requirements of  
**ISO 9001:2015**

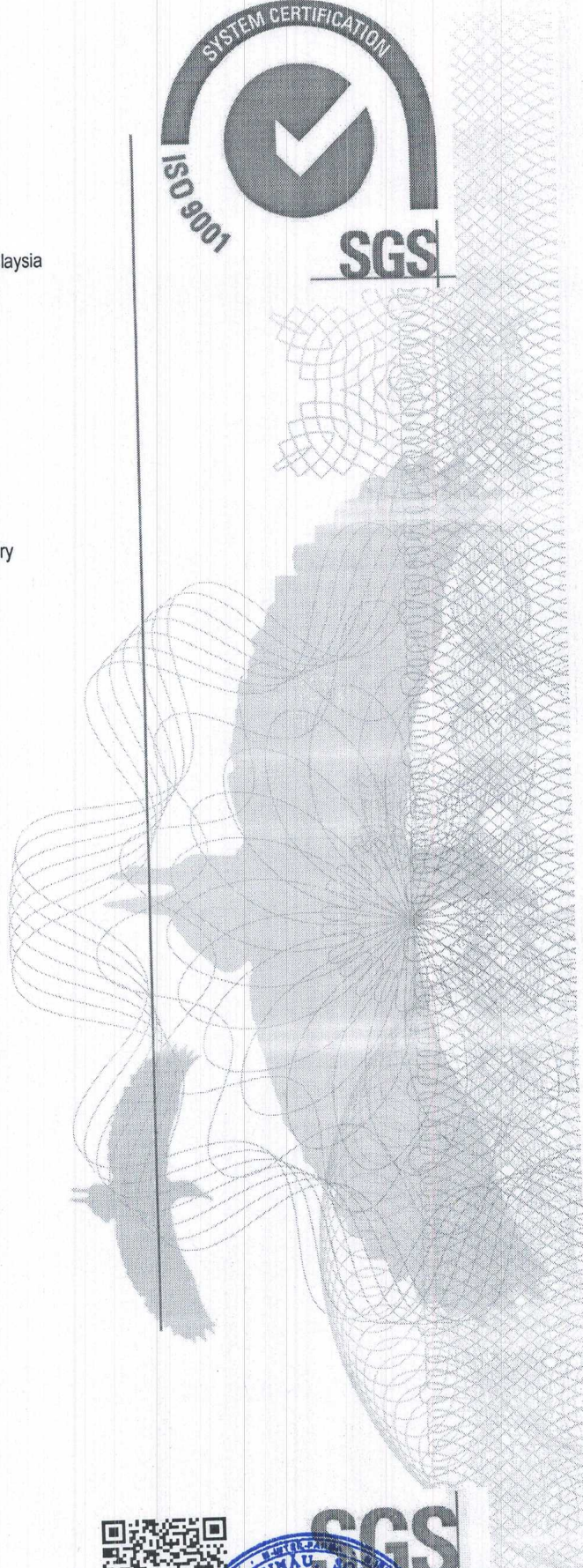
For the following activities  
Manufacture of Sterile/Non-sterile Natural Latex Examination Gloves.  
Manufacture of Sterile Latex Surgical Gloves.

This certificate is valid from 22 July 2022 until 21 July 2025 and remains valid subject to satisfactory surveillance audits.  
Issue 13. Certified since 02 March 2000.  
Certified activities performed by additional sites are listed on subsequent pages.

Authorised by



SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - www.sgs.com



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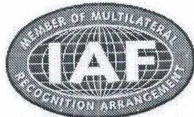
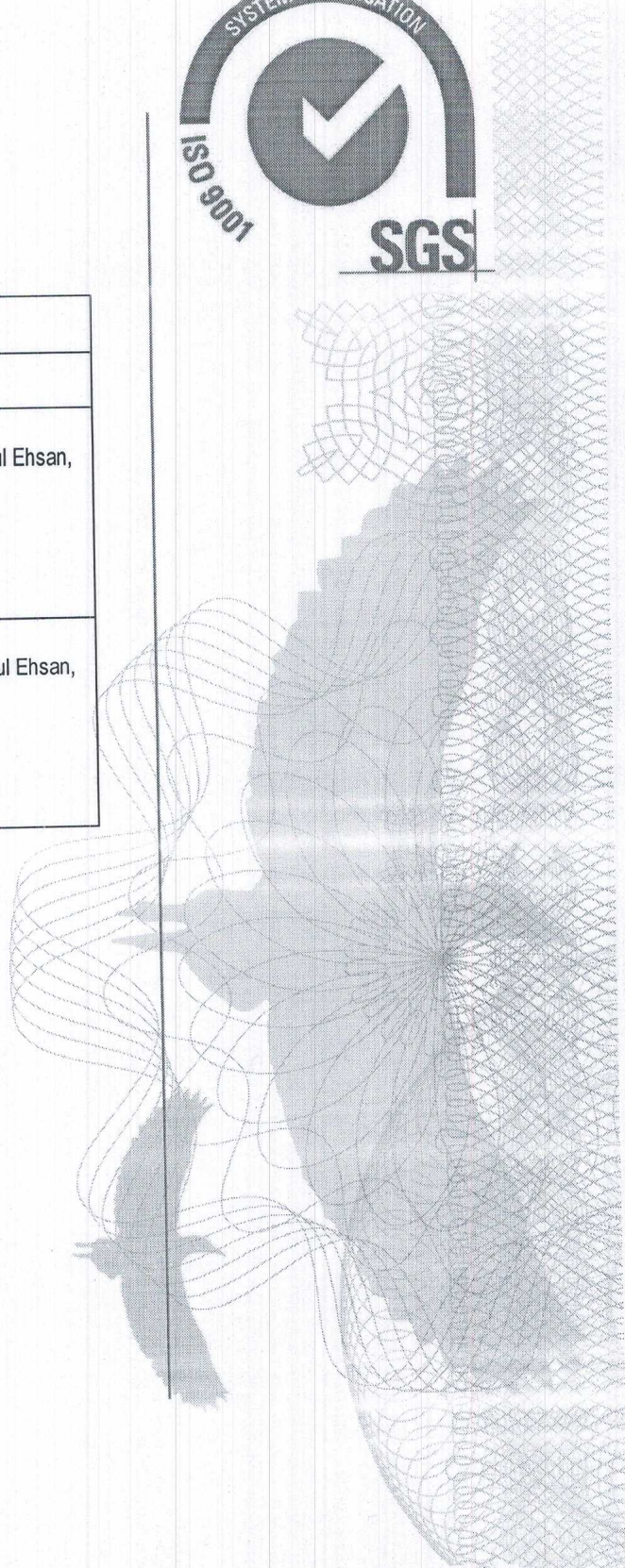


Certificate MY00/51449, continued

# Supermax Glove Manufacturing Sdn. Bhd.

ISO 9001:2015

Issue 13
<b>Sites</b>
Supermax Glove Manufacturing Sdn. Bhd. Lot 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Manufacture of Sterile/Non-sterile Natural Latex Examination Gloves. Manufacture of Sterile Latex Surgical Gloves.
Supermax Glove Manufacturing Sdn. Bhd. Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Manufacture of Sterile/Non-sterile Natural Latex Examination Gloves. Manufacture of Sterile Latex Surgical Gloves.



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Certificate MY00/51448

The management system of

# Supermax Glove Manufacturing Sdn. Bhd.

Lot 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Manufacture of Sterile/Non-sterile Natural Latex Examination Gloves.

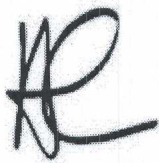
Manufacture of Sterile Latex Surgical Gloves.

This certificate is valid from 11 July 2022 until 22 July 2025 and remains valid subject to satisfactory surveillance audits.

Issue 13. Certified since 02 March 2000.

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by



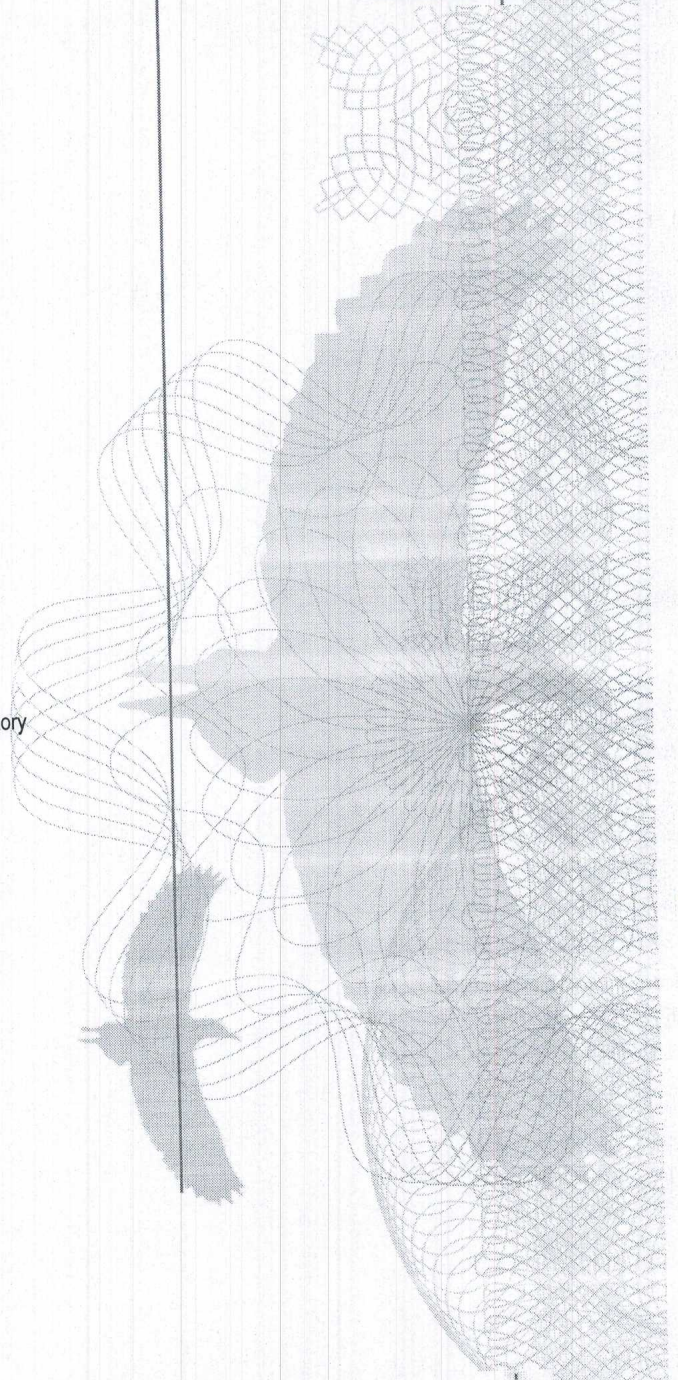
SGS United Kingdom Ltd

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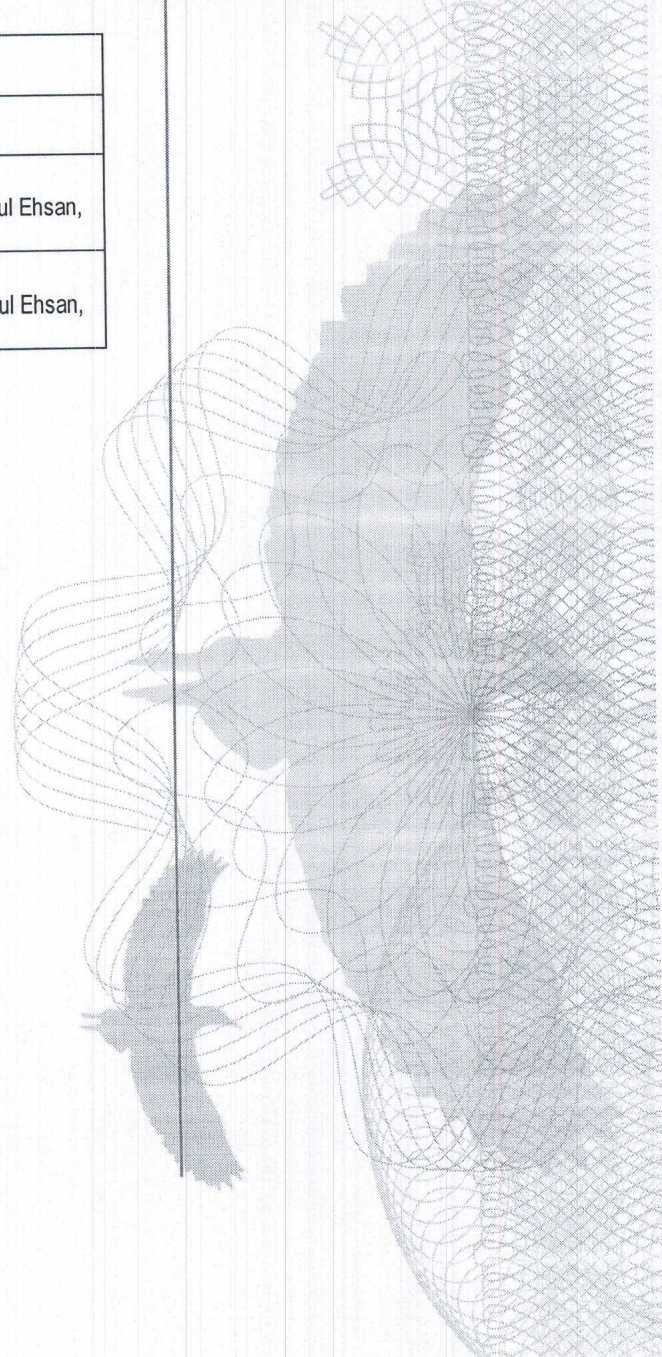


Certificate MY00/51448, continued

# Supermax Glove Manufacturing Sdn. Bhd.

ISO 13485:2016  
EN ISO 13485:2016

Issue 13
<b>Sites</b>
Supermax Glove Manufacturing Sdn. Bhd. Lot 42, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Supermax Glove Manufacturing Sdn. Bhd. Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia



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**SUPERMAX**  
GLOVE MANUFACTURING SDN BHD  
(218698-T)

Lot 38, Putra Industrial Park, Bukit Rahman Putra  
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia  
Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 61452266  
E-MAIL: info@supermax.com.my  
www.supergloves.com

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 9<sup>th</sup> January 2020 contains all the relevant technical information.

**Sungai Buloh, Selangor  
Malaysia**



Yap Peak Geeh  
QA & Regulatory Affairs Manager

