



SUPERMAX
GLOVE MANUFACTURING SDN BHD
(21869S-T)

Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61452328 (30 lines) Fax: 603-61582191 / 61452266
E-MAIL: info@supermax.com.my
http://www.supergloves.com

Nov 08, 2019

To Whom It May Concern:

CERTIFICATE OF CONFORMITY

We, SUPERMAX GLOVE MANUFACTURING SDN. BHD., located at Lot 38, Putra Industrial Park, Bukit Rahman Putra, 40160 Sungai Buloh, Selangor, Malaysia, declare that the medical devices described hereafter,

➤ **“BEYBI GOLD PLUS” LABEL – STERILE LATEX SURGICAL GLOVES, POWDER FREE SMOOTH SURFACE**

6.5 (G/87929)
7.0 (G/87929)
7.5 (G/87929)
8.0 (G/87929)

- Are in conformity with the essential requirements of Medical Device Directive (MDD) 93/42/EEC as amended by Directive 2007/47/EC for Class I non sterile medical devices.
- The gloves are manufactured according to ISO 9001:2015 and ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS UK Ltd Systems & Services Certification, Rossmore Business Park Ellesmere Port Cheshire CH653EN UK.
- Our European Representative is SUPERMAX HEALTHCARE LIMITED., 12-16 Titan Drive, Fengate, Peterborough, PE1 5XN, United Kingdom.

Klang, Selangor
Malaysia



Yap Peak Geeh
QA & Regulatory Affairs Manager

The management system of

Supermax Glove Manufacturing Sdn. Bhd.

Lot 42, Putra Industrial Park, Bukit Rahman Putra
47000 Sungai Buloh, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 20 March 2014
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered MY/KUL/ MY00374

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

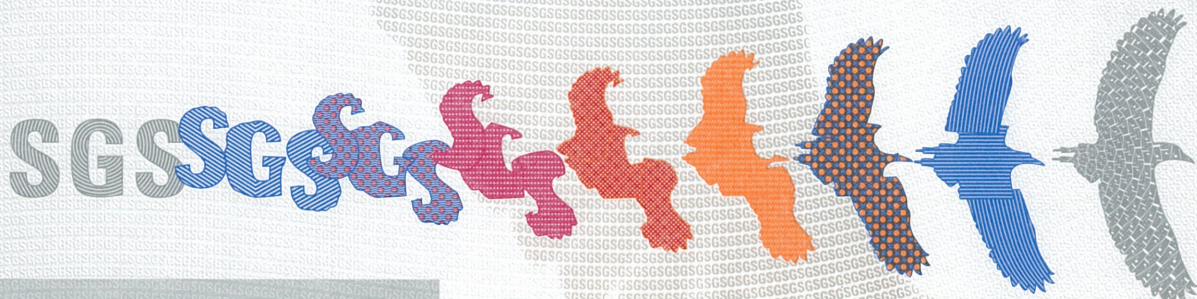
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 Annex V_EN rev. 01

Page 1 of 2



Supermax Glove Manufacturing Sdn. Bhd.

Directive 93/42/EEC on medical devices, Annex V

Issue 1

Detailed scope

**Sterile Natural Latex Powdered Surgical Gloves
Sterile Natural Latex Powder Free Surgical Gloves**

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

Site 2

Lot 38, Putra Industrial Park, Bukit Rahman Putra
47000 Sungai Buloh, Selangor Darul Ehsan
MALAYSIA