

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

Sterile Natural Latex Surgical Gloves

Where the above scope includes class Ib 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.

This certificate is valid from 22 July 2016 until 22 July 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 22 May 2019

Issue 2. Certified since 20 March 2014

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

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EC Certificate Production Quality Assurance System: Certificate MY14/01387,
continued

Supermax Glove Manufacturing Sdn. Bhd.

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

Issue 2

Detailed scope

Sterile Natural Latex 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
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