

EC Certificate Production Quality Assurance System: Certificate MY19/1811030189

The management system of

TG Medical Sdn. Bhd.

Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru
41050 Klang, 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 and Sterile Polyisoprene 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.

This certificate is valid from 16 December 2019 until 06 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 19 November 1999
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered MY/KUL/ MY00308

Authorised by

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 AnnexV_EN rev. 01

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A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 3 : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.

☎ +603 3392 7880/7350 📠 +603 3392 9160 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturer's Name : TG MEDICAL SDN. BHD
Manufacturer's Address : Lot 5091, Jalan Teratai, Batu 5,
Off Jalan Meru, 41050 Klang,
Selangor D. E. Malaysia

European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80, D-47229 Duisburg
Deutschland/Germany
Tel.: +49-(0)2065-76421-0,
Fax: +49-(0)2065-76421-19

Name of Device : Sterile Latex Surgical Gloves
Type : Powdered
Classification : Class IIa
Conformity Route : Annex V and VII
Rule : Rule 7

We herewith declare in our own responsibility that the above-mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).

EC Certificate(s) : MY19/1811030189
EC Certificate(s) valid until : 06 August 2023
Notified Body : SGS Belgium NV
SGS House Noorderlaan
872030 Antwerp Belgium

CE Number : CE 1639
Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010
Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 31st January 2020



Name: Pn Noor Akilah Saidin
Designation: DGM, RA

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 3 : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.

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BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturer's Name : TG MEDICAL SDN. BHD
Manufacturer's Address : Lot 5091, Jalan Teratai, Batu 5,
Off Jalan Meru, 41050 Klang,
Selangor D. E. Malaysia

European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80, D-47229 Duisburg
Deutschland/Germany
Tel.: +49-(0)2065-76421-0,
Fax: +49-(0)2065-76421-19

Name of Device : Sterile Latex Surgical Gloves
Type : Powder Free
Classification : Class IIa
Conformity Route : Annex V and VII
Rule : Rule 7

We herewith declare in our own responsibility that the above-mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).

EC Certificate(s) : MY19/1811030189
EC Certificate(s) valid until : 06 August 2023
Notified Body : SGS Belgium NV
SGS House Noorderlaan
872030 Antwerp Belgium

CE Number : CE 1639
Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010
Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 31st January 2020



Name: Pn Noor Akilah Saidin
Designation: DGM, RA

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 3 : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.
☎ +603 3392 7880/7350 📠 +603 3392 9160 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturer's Name : TG MEDICAL SDN. BHD
Manufacturer's Address : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru,
41050 Klang, Selangor D. E. Malaysia

European Authorized Representative: Top Glove Europe GmbH
Bliersheimer Str. 80, D-47229 Duisburg
Deutschland/Germany
Tel.:+49-(0)2065-76421-0,
Fax:+49-(0)2065-76421-19

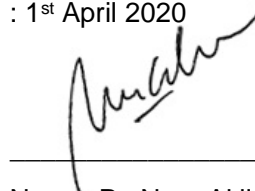
Name of Device : Nitrile Examination Gloves
Type : Powder Free
Classification : Class I, Non Sterile
Conformity Assessment Procedure : Annex VII
Conformity Route : Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark are fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010
Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 1st April 2020



Name: Pn Noor Akilah Saidin
Designation: RA Deputy General Manager

TG MEDICAL**TOP QUALITY, TOP EFFICIENCY****TG MEDICAL SDN. BHD.****The World's Largest Rubber Glove Manufacturer****GOOD HEALTH, SAFETY FIRST & BE HONEST**

(Company No. 283358-W)

(GST ID: 001289224192)

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 3

: Lot 5091, Jln Teratai, 5th Miles, Off Jln Meru, 41050, Klang, Selangor D.E. Malaysia.

☎ +603-3392 7880/7350 📠 +603-3392 7229/9160 📠 +6012-2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION

: To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES

: 34 Factories (Malaysia, Thailand & China), 581 Production Lines, 55.8 Billion Gloves Per Annum, 12,000 Employees.

MARKET

: Exports to 195 countries worldwide with Marketing Offices in the USA and Germany.

DECLARATION OF CONFORMITY

Original Manufacturer's Name : TG MEDICAL SDN. BHD
 Original Manufacturer's Address : Lot 5091, Jalan Teratai, 5th Mile, Off Jalan Meru,
 41050 Klang, Selangor D. E. Malaysia

European Authorized Representative: Top Glove Europe GmbH
 Bliersheimer Str. 80, D-47229 Duisburg
 Deutschland/Germany
 Tel.:+49-(0)2065-76421-0, Fax:+49-(0)2065-76421-19

Name of Device : Latex Surgical Gloves
 Type : Powdered and Powder Free Glove
 Classification : Class IIa, Sterile
 Conformity Assessment Procedure : Annex V
 Conformity Route : CE 0120

We herewith declare in our own responsibility that the above-mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).

EC Certificate(s) : MY99/51109
 EC Certificate(s) valid until : 14 September 2021
 Notified Body : SGS United Kingdom Ltd. Systems & Services
 Certification
 Competent Authority : Bezirksregierung Düsseldorf,
 Postfach 300865, 40408 Düsseldorf.
 Registration Date : 31 March 2010
 Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 17th May, 2018



Name: Noor Akilah Bte Saidin
 Designation: DGM- RA
 (RA/DOC/030/04/2018)

EC Certificate Production Quality Assurance System: Certificate MY99/51109

The management system of

TG Medical Sdn. Bhd.

Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru
41050 Klang, 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 and Sterile Polyisoprene Surgical Gloves.

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 06 August 2018 until 06 August 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 February 2021
Issue 9. Certified since 19 November 1999

Certification is based on reports numbered MY/KUL MY00308

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
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SGS CE 13 0311

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