

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

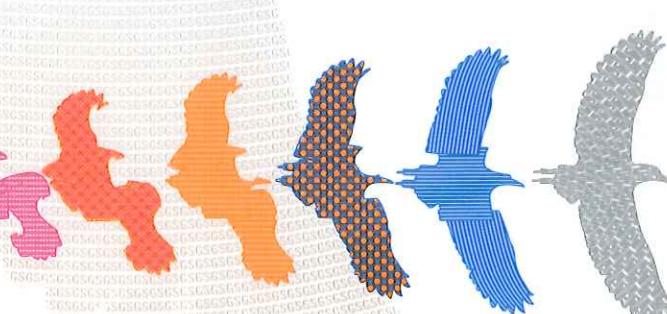


SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
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LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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TG MEDICAL**TOP QUALITY, TOP EFFICIENCY****TG MEDICAL SDN. BHD.****The World's Largest Manufacturer of Gloves****GOOD HEALTH, SAFETY FIRST & BE HONEST****Company No.**

199301028620 (283358-W)

SST ID: B10-1808-22000011

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.

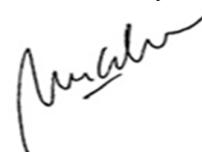
Registration Date

: 31 March 2010

Registration No

: DE/CA20/02-TOPGLOVEB-01/10

Date

: 31st January 2020

Name: Pn Noor Akilah Saidin

Designation: DGM, RA

TG MEDICAL**TOP QUALITY, TOP EFFICIENCY****TG MEDICAL SDN. BHD.****The World's Largest Manufacturer of Gloves****GOOD HEALTH, SAFETY FIRST & BE HONEST****Company No.**

199301028620 (283358-W)

SST ID: B10-1808-22000011

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

: 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

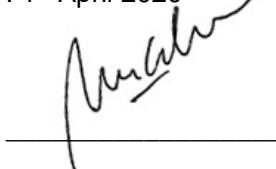
: 31 March 2010

Registration No

: DE/CA20/02-TOPGLOVEB-01/10

Date

: 1st April 2020



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

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)

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
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311

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