



TG MEDICAL SDN. BHD.
The World's Largest Manufacturer of Gloves
GOOD HEALTH, SAFETY FIRST & BE HONEST

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

FACILITIES : 50 Factories (Malaysia, Thailand, Vietnam & China), 800 Production Lines, 100 Billion Gloves Per Annum, 22,000 Employees.

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

Date: 11th August 2023
To: Whom it may concern

SUB: Letter of Declaration

We, **TG Medical Sdn. Bhd.** hereby confirm that;

- below listed medical devices are manufactured by our company and continue to conform 93/42/EEC Medical Devices Directive,
- below listed medical devices do not pose any unacceptable risk towards the health or security of patients, users or other persons or other matters related to protection of public health,
- there is no change in the design and intended use of below listed medical devices
- our company has a Quality Management System according to ISO 13485 valid by 6th August 2024

Our company has a Quality Management System according to ISO 14001 valid by 6th August 2021			
Manufacturer's name	TG Medical Sdn. Bhd.		
Manufacturer's address	Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan Malaysia		
Contact person in manufacturer	Name	E-mail address	Phone no
	Fatimawati Mohamad	fatimawati@topglove.com.my	+6019-255 1419
Description of the medical devices	Sterile Latex Surgical Powder Free Gloves (Basic UDI-DI no 955583990800Q3) Sterile Latex Surgical Powdered Gloves (Basic UDI-DI no 955583990760QG)		
MDD 93/42/EEC EC Certificate			
EC Certificate No	MY19/1811030189		
Notified Body	SGS Belgium NV, SGS House Noorderlaan, 872030 Antwerp Belgium.		
Notified Body's ID no	1639		

Before 26 May 2024, we applied to the Notified Body in accordance with section 4.3, second subparagraph of Annex 7 to MDR 2017/745 for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device. Details of the application are given below:

Application date	18th February 2022
Notified Body	SGS Belgium NV
Notified Body's ID no	1639
Medical devices in scope of application	Sterile Latex Surgical Powder Free Gloves (Basic UDI-DI no 955583990800Q3) Sterile Latex Surgical Powdered Gloves (Basic UDI-DI no 955583990760QG)

Before 26 September 2024, we and the Notified Body signed a written agreement in accordance with section 4.3, second subparagraph of Annex 7 to this Regulation (MDR 2017/745) for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device. Details of the agreement are given below:

Agreement date	25th May 2022
Notified Body	SGS Belgium NV
Notified Body's ID no	1639
Medical devices in scope of agreement	Sterile Latex Surgical Powder Free Gloves (Basic UDI-DI no 955583990800Q3) Sterile Latex Surgical Powdered Gloves (Basic UDI-DI no 955583990760QG)

LOD Validity: 11th August 2023 to 10th August 2024

Name/title : Noor Akilah Binti Saidin/ General Manager, RA
Date/place : 11th August 2023/ Klang, Malaysia
RA/LOD/R2/020/08/23/15/M

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

DP 25/03/21/TGT