TG MEDICAL
TOP QUALITY, TOP EFFICIENCY

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.

+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 : 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.

DECLARATION OF CONFORMITY (DoC)

Name of Device: Sterile Latex Surgical Powdered Glove

Manufacturing Site

TG Medical Sdn. Bhd.

Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru,

41050, Klang, Selangor D.E., Malaysia

MDR 2017/745

Single Registration Number	: MY-MF-000009606 (Manufacturing Site SRN)
European Authorized Representative	: Top Glove Europe GmbH Bliersheimer Str. 80, D-47229 Duisburg, Germany.
Single Registration Number	: DE-AR-000004968 (EAR SRN)
Classification Rule	: Rule 7, Class IIa
Conformity Assessment Procedure	: Annex IX (Chapter I)
Brand	: MUMU
Basic UDI – DI	: 955583990760QG
EC Certificate(s) number	: MY24/00000440
EC Certificate(s) valid until	: 27 September 2029
Notified Body	: SGS Belgium NV, SGS House Noorderlaan, 872030 Antwerp Belgium
CE Marking	: CE 1639
Applicable Standards	: Attachment I

Intended use: Sterile Latex Surgical Powdered Glove is intended to be worn by operating room personnel to prevent the transmission of infections or cross contamination between patient and user.

Conclusion:

This declaration of conformity is issued under the sole responsibility of TG Medical Sdn. Bhd. We hereby declare that the medical device (s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by SGS Belgium NV. All supporting documentation is retained at the premises of the manufacturer.

DoC Validity Date : 5th December 2024 until 4th December 2027

Shipment Territory : Turkey

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Date: 4th December 2024

ATTACHMENT I: LIST OF APPLICABLE STANDARDS AND REFERENCE FOR MDR 2017/745

Applicable Standards:

No	Standard	Descriptions	Date Published
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2	EN 455-1:2020+A1:2022	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
3	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
4	EN 455-3:2023	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation	April 2015
5	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
6	EN ISO14971:2019/A11:2021	Medical device - Application of risk management to medical devices.	December 2021
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	June 2021
9	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products – Requirements for validation and routine control–Radiation sterilization	November 2019
11	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015

No	Standard	Descriptions	Date Published
12	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
14	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	June 2021
17	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
18	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
19	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
20	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
21	EN 62366-1/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
22	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
23	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
24	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
25	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
26	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
27	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017

No	Standard	Descriptions	Date Published
28	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
30	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
31	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
32	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
33	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
34	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017