TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

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

Registration No.
199101010171 (220483-T)
SST ID: B16-1808-22000008

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

FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.

+603 3392 1992 +603 3392 1291/8410 +6012 2896 270 sales@topglove.com.my www.topglove.com

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

FACILITIES : 47 Factories (Malaysia, Thailand, Vietnam & China), 750 Production Lines, 90 Billion Gloves Per Annum, 21,000 Employees.

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

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site	: TOP GLOVE SDN. BHD Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.
Manufacturer's Single Registration Number (SRN)	: MY-MF-000009690
European Authorized Representative	: Top Glove Europe GmbH Bliersheimer Str. 80A, 47229 Duisburg Germany Tel.: +49-(0)2065-76421-0, Fax: +49-(0)2065-76421-19
European Authorized Representative's Single Registration Number (SRN)	: DE-AR-000004968
Name of Device	: Latex Powder Free Polymer Glove (Palm Textured/Embossed Outside, Natural)
Sales Order Number	: 5400009233
PO Number	: TG001/22
Brand Name	: PPS
Classification	: Class I, Non Sterile
Conformity Assessment Procedure	: Annex I, Annex ll and Annex IV (Self declared)
Rule	: Rule 5

Size	Lot Number	Quantity	Unit	Manufacturing Date	Expiry Date
XS	236009233LLZA	400,000	pcs	2022-03-06	2027-03-05
S	236009233LLZA	800,000	pcs	2022-03-06	2027-03-05
M	236009233LLZA	300,000	pcs	2022-03-06	2027-03-05

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer

Applicable Standards:

No.	Standard	Descriptions	Date Published
1.	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
2.	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
3.	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
4.	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
5.	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019
6.	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices	April 2015
7.	EN ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
8.	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
9.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process	December 2020
10.	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009
11.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	August 2013
12.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018
13.	ISO 10993-12:2021	Biological evaluation for medical devices - Sample preparation and reference materials	January 2021
14.	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation	January 2021
15.	ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied: General requirements.	July 2021
16.	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017

No.	Standard	Descriptions	Date Published
17.	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017
18.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
19.	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
20.	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
21.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
22.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
23.	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
24.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
25.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
26.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
27.	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
28.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex lll	Post Marketing Surveillance (PMS)	April 2017
29.	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
30.	MDR 2017/745	Medical Device Regulation	April 2017

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DoC Issuance Date : 29th March 2022
DoC Expiry Date : 28th March 2023

Delivery Date : 29th March 2022

Basic UDI – DI : 955760100560GG

Name: Rahayu Binti Mat Zin
Designation: Senior Manager, QA
DOC/6336/5400009233/010/00