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.
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
Single Registration Number (SRN)	: DE-AR-000004968
Name of Device	: Nitrile Examination Gloves
Type	: Powder Free
Basic UDI – DI	: 955760101940H5
Brand Name	: Mumu Premium
Size	: XS, S, M, L, XL
Classification (MDR)	: Class I, Non Sterile
Classification (PPER)	: Category III
Conformity Assessment Procedure (MDR)	: Annex I, Annex II and Annex IV (Self declared)
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
Rule (MDR)	: Rule 5
Product Group Reference	: EB201 (ENW35)
EU Type Examination Certificate Number (PPER)	: 2777/10648-05/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777

We, Top Glove Sdn Bhd herewith declare with our own responsibility that abovementioned product;

i. is fully compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer

ii. is following to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 374-1:2016, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 and EN 16523-1:2015.

iii. is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

Applicable Standards (MDR) :

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.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	April 2021
6.	EN 62366-1:2015+A1:2020	Medical Devices-Part 1: Application of usability engineering to medical devices	August 2020
7.	EN ISO 14971:2019+A11:2021	Medical device - Application of risk management to medical device.	December 2021
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	Dec 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	May 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

No.	Standard	Descriptions	Date Published
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
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.	ISO/TR 20416	Medical devices — Post-market surveillance for manufacturers	July 2020
30.	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
31.	MDR 2017/745	Medical Device Regulation	April 2017

EU DoC Validity Date : 3rd October 2022 until 2nd October 2023

Name: Pn Noor Akilah Saidin
Designation: RA General Manager
Place of Issue: Klang, Selangor, Malaysia