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
Classification	: Class I, Non Sterile
Brand Name	: i. FAVORIT Soft Blue ii. FAVORIT Soft White iii. FAVORIT Soft Pink iv. FAVORIT Soft Violet v. FAVORIT Max White vi. FAVORIT Max Blue
Size	: XS, S, M, L, XL
Conformity Assessment Procedure	: Annex I, Annex II and Annex IV (Self declared)
Rule	: Rule 5
Intended use	: The gloves are intended to be worn on the hand of healthcare personnel during medical examination procedures to protect cross contamination between healthcare personnel and patient.

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.	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	April 2021
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	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
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

No.	Standard	Descriptions	Date Published
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	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
24.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
25.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
26.	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
27.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
28.	ISO/TR 20416	Medical devices — Post-market surveillance for manufacturers	July 2020
29.	MDR 2017/745	Medical Device Regulation	April 2017

EU DoC Validity Date : 8th June 2023 until 7th June 2024
Basic UDI DI : 955760101940H5

Name: Pn Noor Akilah Saidin
Designation: RA General Manager