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.

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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 Powder Free Gloves
Product Code	: NPF
Classification (MDR)	: Class I
Classification (PPER)	: Category III
Rule (MDR)	: Rule 5
Conformity Assessment Procedure (MDR)	: Annex I, Annex II, Annex III and Annex IV (Self declared)
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
Sizes	: XS, S, M, L, XL
Applicable Standards (MDR)	: Attachment I
Product Group Reference	: EB201
EU Type Examination Certificate Number (PPER)	: 2777/10648-06/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777
Intended use (MDR)	: 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 Top Glove Sdn Bhd herewith declare with our own responsibility that the abovementioned product;

i. is fully compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by TUV SUD Product Service GmbH. 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 21420:2020, EN ISO 374-1:2016+A1:2018 (EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019) and EN ISO 374-5:2016 .

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.

Basic UDI – DI (MDR) : 955760101940H5

DoC Validity Date : 9th October 2023 until 8th October 2024

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Place: Klang, Malaysia.
Effective Date: 9th October 2023

Attachment I

Applicable Standards (MDR) :

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.	February 2022
3.	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
4.	EN 455-3:2015	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 devices - Application of risk management to medical devices (ISO 14971:2019)	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 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a riskmanagement process (ISO 10993-1:2018)	December 2020
9.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
10.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
11.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
12.	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	May 2020
13.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
14.	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
15.	EN 62366-1/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020

No	Standard	Descriptions	Date Published
16.	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
17.	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
18.	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
19.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
20.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
21.	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
22.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
23.	MEDDEV 2.7/1	Clinical Evaluation	Revision 4, June 2016
24.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
25.	MEDDEV 2.12/1	Medical Device Vigilance System	Revision 8, January 2013
26.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
27.	MEDDEV 2.12/2	Post Market Clinical Follow-up Studies	Revision 2, January 2012