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.

DECLARATION OF CONFORMITY

Manufacturing Site	: TOP GLOVE SDN. BHD. Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan, Malaysia.
Name of Device	: Nitrile Examination Gloves
Type	: Powder Free
Classification	: PPE Category III

I, the undersigned, hereby declare that the disposable device(s) specified above are following 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 and EN 374-5:2016.

Issued by	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

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 is identical to the PPE (EU) Certificate of Conformity No: **2777/10648-04/E00-00.**

DoC Validity : 30th June 2021 to 29th June 2022

Noor Akilah Bt Saidin
General Manager, RA
RA/DOCPPE/R2/041/06/21/08/NPFN/M

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

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EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site	: TG MEDICAL SDN. BHD. : Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.
Single Registration Number (SRN)	: TBA
European Authorized Representative	: Top Glove Europe GmbH Bliersheimer Str. 80 A, 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	: Dr. Mayer Life & Health
Size	: XS, S, M, L, XL
Conformity Assessment Procedure	: Annex I, Annex II and Annex IV (Self declared)
Rule	: Rule 5

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 ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
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.	ISO 10993-1:2018	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process	Aug 2018
9.	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009
10.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	Feb 2014
11.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018
12.	ISO 10993-12:2012	Biological evaluation for medical devices - Sample preparation and reference materials	June 2012
13.	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements.	Nov 2016
14.	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
15.	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017
16.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
17.	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
18.	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
19.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017

No.	Standard	Descriptions	Date Published
20.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
21.	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
22.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
23.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
24.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
25.	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
26.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
27.	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
28.	MDR 2017/745	Medical Device Regulation	April 2017
29.	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices	April 2015

EU DoC Validity Date : 30th June 2021 to 29th June 2022
Basic UDI – DI : 955100419010AV

Name: Pn Noor Akilah Saidin
Designation: RA General Manager

TG MEDICAL SDN. BHD.

PRODUCT SPECIFICATION
Nitrile Powder Free Examination Gloves Finger Textured

SECTION I: PRODUCT DESCRIPTION

1. 1	Type	Nitrile Examination Glove, Powder Free, Online Single Chlorinated, Non sterile
1. 2	Material	100% Synthetic Nitrile Latex
1. 3	Color	Black
1. 4	Design and Feature	Ambidextrous, finger textured, beaded cuff
1. 5	Powder	No powder lubricant added
1. 6	Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
1. 7	Shelf Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 8	Packing Style	100 pcs gloves x 10 dispensers x 1 carton
1. 9	Size Marking	The size of gloves shall be marked in the check box on every carton with black ink.

SECTION II: PERFORMANCE REQUIREMENTS

Sampling Plan : ISO 2859 Single Normal

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	Median of 13 test pieces		EN455-2 : 2015
2.2	Physical Properties	Median of 13 test pieces		EN455-2 : 2015
2.3	Freedom from Holes Water Tight Test	GI	1.5	EN455-1 : 2020
2.4 i ii	Visual Defects: Major Visual Minor Visual	GI	 2.5 4.0	In-house practice
2.5 i ii iii	Packaging Defects: Regulatory Visual Critical incl. Gloves Counting	 GI GI S2	 ** 4.0 4.0	In-house practice
2.6	Powder Free Residue	N=5	N/A	EN455-3 : 2015 ASTM D6319-19 ASTM D6124-06 (2017)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

TG MEDICAL SDN. BHD.

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length, mm	All Sizes	Min 240
Palm Width, mm	XS S M L XL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3
Thickness, mm *single wall	All Sizes	Finger : 0.09 +/- 0.02 Typical value: 0.09 to 0.11 Palm : 0.07 +/- 0.02 Typical value: 0.06 to 0.07

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Median Force at Break, N	Min 6 Typical value: 6 to 8	Min 6 Typical value: 6 to 8

3.3 Freedom from Holes

The sample size and allowable number of non conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects

The sample size and allowable number of non conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects

The Sample size and allowable number of non conforming in the samples for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements, Gloves Counting=100 pcs by count per Dispenser.

3.6 Powder Free Residue

Maximum 2 mg per glove

Prepared by:
Product Management Unit

Date: 14th October 2020

Checked by:
Fatimawati Bt Mohamad
Manager, RA

Approved by:
Noor Akilah Saidin
Deputy General Manager, RA