

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	: BLOW GLOVE
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.

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

DP 03/11/20/TGT

Applicable Standards:

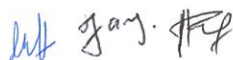
No	Standard	Descriptions	Date Published
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
3	EN 455-3:2015	Medical gloves for 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 ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
6	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices	April 2015
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	August 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.	August 2013
11	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018
12	ISO 10993-12:2021	Biological evaluation for medical devices - Sample preparation and reference materials	January 2021
13	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation	January 2021
14	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied: General requirements.	July 2021
15	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
16	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017

No	Standard	Descriptions	Date Published
17	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
18	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
19	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
20	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
21	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
22	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
23	MEDDEV 2.12/1	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	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
29	MDR 2017/745	Medical Device Regulation	April 2017
30	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical device	December 2019

EU DoC Validity Date
Basic UDI – DI

: 19th April 2023 until 18th April 2024
: 955760101940H5


Name: Ph. Noor Akilah Saidin
Designation: RA General Manager



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DECLARATION OF CONFORMITY

Manufacturing site : **TOP GLOVE SDN. BHD.**
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor D.E., Malaysia.

Name of Device : Nitrile Examination Gloves
Type : Powder Free
Classification : PPE Category III
Product Reference : EB201

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, EN420:2003+A1:2009, EN374-2:2014, EN374-4:2013 and EN374-5:2016.

Issued by : SATRA Technology Europe Ltd,
Bracetown Business Park,
Clonee, DIS YN2P,
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 Ltd, Bracetown Business Park, Clonee, DIS YN2P, Ireland is identical to the PPE EU Certificate of Conformity No: **2777/10648-05/E00-00**.

DoC Validity Date : 26th April 2023 until 16th August 2023



Noor Akilah Bt Saidin
General Manager, RA
RA/DOCPPE/R3/016/04/23/10/NPFN/M

