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)	: TBA
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	: Latex Examination Gloves
Type	: Powdered
Classification	: Class I, Non Sterile
Brand Name	: PPS Glove
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 ISO 14971:2019	Medical device - Application of risk management to medical device.	Dec 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	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
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016

No	Standard	Descriptions	Date Published
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 lll	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 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019

EU DoC Validity Date : 11th June 2021 to 10th June 2022
Basic UDI – DI : 955100430340AC

Name: Pn Noor Akilah Saidin
Designation: RA General Manager

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Single Registration Number (SRN)	: TBA
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	: Latex Examination Gloves
Type	: Polymer Powder Free
Classification	: Class I, Non Sterile
Brand Name	: PPS Glove
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.

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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
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016

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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 lll	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 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019

EU DoC Validity Date : 11th June 2021 to 10th June 2022
Basic UDI – DI : 955100430330A9

Name: Pn Noor Akilah Saidin
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Single Registration Number (SRN)	: DE-AR-000004968
Name of Device	: Nitrile Examination Gloves
Type	: Powder Free
Classification	: Class I, Non Sterile
Brand Name	: PPS Glove
Size	: XS, S, M, L, XL
Conformity Assessment Procedure	: Annex I, Annex II and Annex IV (Self declared)
Rule	: Rule 5

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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 lll	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 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019

EU DoC Validity Date : 11th June 2021 to 10th June 2022
Basic UDI – DI : 955100430350AF

Name: Pn Noor Akilah Saidin
Designation: RA General Manager