

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 +6012 2896 270 sales@topglove.com.my www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 63.9 Billion Gloves Per Annum, 18,000 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.

Manufacturer's 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

European Authorized Representative's
Single Registration Number (SRN) : TBA

Name of Device : Latex Examination Powdered Glove

Sales Order No : 2000129198
PO No : TP/20-01/12
Brand Name : SAFEPLAST

Classification : Class I, Non Sterile
Conformity Assessment Procedure : Annex I, Annex II and Annex IV(Self declaration)
Rule : Rule 5

Size	Lot Number	Quantity	Unit	Manufacturing Date	Expiry Date
S	TP/20-01/12	290,000	pcs	2021-03	2026-02
M	TP/20-01/12	540,000	pcs	2021-03	2026-02
L	TP/20-01/12	270,000	pcs	2021-03	2026-02
XL	TP/20-01/12	100,000	pcs	2021-03	2026-02

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 retain under the premise of manufacturer.

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BE HONEST AND NO CHEATING"**

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Applicable Standards:

No	Standard	Descriptions	Date Published
1	EN 455-1:2000	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	October 2000
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 14971:2012	Medical device - Application of risk management to medical device.	July 2012
6	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
7	ISO 10993-1:2018	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process	Aug 2018
8	ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	June 2009
9	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	Feb 2014
10	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018
11	ISO 10993-12:2012	Biological evaluation for medical devices - Sample preparation and reference materials	June 2012
12	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

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No	Standard	Descriptions	Date Published
13	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
14	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017
15	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
16	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
17	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
18	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
19	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
20	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
21	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
22	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
23	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
24	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
25	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017

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No	Standard	Descriptions	Date Published
26	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
27	MDR 2017/745	Medical Device Regulation	April 2017

Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010

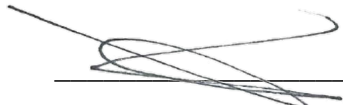
Registration No : DE/CA20/02-TOPGLOVEB-04/13

DoC Issuance Date : 30th April 2021

DoC Expiry Date : 29th April 2022

Delivery Date : 9th April 2021

Basic UDI – DI : 955100429330BV



Name: Ms. Khoo Wai Woon
Designation: Manager, QA
DOC/1112/2000129198/130/01