DURAMEDICAL
TOP QUALITY, TOP EFFICIENCY

DURAMEDICAL SDN. BHD.

GOOD HEALTH, SAFETY FIRST & BE HONEST

Company No.
199901007009 (481909-U)
SST ID: B10-1808-21024928

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 39DD : Lot 4962, Jalan Teratai, Batu 6 Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.

+603 7890 3339 (Ext:2002) +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, 64 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	: DURAMEDICAL SDN. BHD. : Lot 4962, 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 Dental Dam
Classification	: Class I, Non Sterile
Brand Name	: Prima
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 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
2.	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
3.	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices.	April 2015
4.	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019
5.	EN ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
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	August 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.	February 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.	November 2016
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

No.	Standard	Descriptions	Date Published
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
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

EU DoC Validity Date : 2nd July 2021 to 1st July 2022
Basic UDI – DI : 955598250118NL

Name: Pn Noor Akilah Saidin
Designation: RA General Manager