



**TERANG NUSA (MALAYSIA)
SDN. BHD.**

GOOD HEALTH, SAFETY FIRST & BE HONEST

Company No.
199101013885 (224197-U)
SST ID: D10-1808-22000001

A member of Top Glove Group: The World's Largest Manufacturer of Gloves

FACTORY 36

: 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan D.N., Malaysia.

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+609 771 3565/3072

+6012 2896 270

sales@topglove.com.my

www.topglove.com

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site	: TERANG NUSA (MALAYSIA) SDN. BHD : Terang Nusa (Malaysia) Sdn. Bhd. 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan, Malaysia.
Single Registration Number(SRN)	: TBA
European Authorized Representative	: Ulma International GmbH Pfaffenweg 35 89231 Neu-Ulm, Germany
Single Registration Number (SRN)	: TBA
Name of Device	: Nitrile Examination Gloves
Type	: Powder Free
Device Reference code (PPER)	: 10-050-1 XS 10-050-2 S 10-050-3 M 10-050-4 L 10-050-5 XL
Basic UDI-DI	: 955507610000G8
Brand Name	: Nugard Nitril
Size	: XS, S, M, L, XL
Classification (MDR)	: Class I, Non Sterile
Classification (PPER)	: Category III
Conformity Assessment Procedure (MDDR)	: Annex I, Annex II and Annex IV (Self declared)
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
Rule	: Rule 5
EU Type Examination Certificate Number (PPER)	: 2777/10580-02/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777

DOC OP3:R4
RA/DOC/MDRPPE/TNM/NPFN/OP3/NN/10/001/08/21/R1

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Juayn
DP 21/01/20/TGT

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- We Top Glove Sdn Bhd herewith declare with our own responsibility that above mentioned product;
- is fully compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer
 - is following to 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/Type B, EN 420:2003+A1:2009, EN 374-2:2014, EN 374-4:2013, EN 374-5:2016 (protecting against virus, bacteria and fungi) and EN 16523-1:2015.
 - 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.

Applicable Standards (MDR) :

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

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Signature

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TERANG NUSA

TOP QUALITY, TOP EFFICIENCY

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No	Standard	Descriptions	Date Published
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 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements.	July 2021
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
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 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019

EU DoC Issuance Date

: 31st March 2021

Name: Pn Noor Akilah Saidin

Designation: RA General Manager

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