TERANG NUSA
TOP QUALITY, TOP EFFICIENCY

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.

+609 774 7171 +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.
European Authorized Representative	: Ulma International GmbH Pfaffenweg 35 89231 Neu-Ulm, Germany
Name of Device	: Sterile Latex Surgical Glove
Type	: Powder Free
New Device Reference Code (PPER)	: TNMSA203
Previous Device Reference code (PPER)	: 406-1113-1, 5.5 406-1113-2, 6.0 406-1113-3, 6.5 406-1113-4, 7.0 406-1113-5, 7.5 406-1113-6, 8.0 406-1113-7, 8.5 406-1113-8, 9.0
Brand Name	: Maxitex Ortho
Size	: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Classification (MDD)	: Class IIa
Classification (PPER)	: Category III
Conformity Assessment Procedure (MDD)	: Annex II excluding 4
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
EU Type Examination Certificate Number (PPER)	: 2777/10569-02/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777
Notified Body Number (MDD)	: 0123
Notified Body (MDD)	: TÜV SÜD Product Service GmbH, Ridlerstraße 65 80339, Munich, Germany.
EC Certificate Number (MDD)	: G1 061155 0014 Rev. 02
EC Certificate (MDD) valid from	: 19th February 2021
EC Certificate (MDD) valid until	: 26th May 2024

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We Terang Nusa (Malaysia) Sdn Bhd herewith declare with our own responsibility that above mentioned product with CE mark;

i. Meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).

ii. 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.

iii. 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 under MDD :

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	ISO 2859-1:2011	Sampling procedures and table for inspection by attributes	June 2011
7	ISO 11737-1:2018/AMD 1:2021	Sterilization of medical device - Microbiological methods estimation of population of microorganisms on product - Amendment 1	May 2021
8	ISO 11737-2:2019	Sterilization of medical device - Microbiological methods - Test of sterility performed I the validation of a sterilization process.	December 2019
9	ISO 11137-1:2015	Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization	July 2015
10	ISO 11137-2:2013	Sterilization of health care products - Establishing the sterilization dose	June 2013
11	ISO 10993-1:2018	Biological evaluation for medical device - Evaluation & Testing	August 2018

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No	Standard	Descriptions	Date Published
12	ISO 10993-5:2009	Biological evaluation of medical devices – Tests for in vitro cytotoxicity	June 2009
13	ISO 10993-10:2010	Biological evaluation for medical device - Tests for irritation and delayed-type hypersensitivity.	August 2010
14	ISO 10993-12:2021	Biological evaluation for medical device - Sample preparation and reference materials	Jan 2021
15	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Requirements for materials, sterile barrier systems and packaging systems.	Jan, 2020
16	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Validation requirements for forming, sealing and assembly processes.	Jan, 2020
17	ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements.	July 2021
18	EN 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices	April, 2015
19	MEDDEV 2.1/1	2.1/1 Definition of Medical Device, Accessory and Manufacturer	April 1994
20	MEDDEV 2.4/1	2.4/1 Classification of Medical Device	Revision 9, June 2010
21	MEDDEV 2.5.1/Rec 1	2.5.1 Technical Documentation	Revision 4, February 2000
22	MEDDEV 2.5/5	2.5/5 Translation Procedure	Revision 3, February 1998
23	MEDDEV 2.5/9	2.5/9 Implication of the Medical Device Directive 9342EEC in Relation to Medical Device Containing Natural Rubber Latex	Revision 1, February 2004
24	MEDDEV 2.5/10	2.5/10 Guideline for Authorized Representative	January 2010
25	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
26	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
27	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
28	MEDDEV 2.12/Rec 1	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000

EU DoC Issuance Date : 27th October 2022

Name: Pn Noor Akilah Saidin
Designation: RA General Manager
RA/DOC/MDDPPE/TNM/LSPF/10/003/12/22/R1