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.

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EU DECLARATION OF CONFORMITY

Manufacturing Site	: Terang Nusa (Malaysia) Sdn. Bhd. : 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan D.N., Malaysia.
European Authorized Representative	: Ulma International GmbH Pfaffenweg 35, 89231 Neu-Ulm, Germany.
Name of Device	: Sterile Latex Surgical Gloves
Type	: Powder Free
New Device Reference Code (PPER)	: TNMSA201
Previous Device Reference Code (PPER)	: 85-154-1, 5.5 85-154-2, 6.0 85-154-3, 6.5 85-154-4, 7.0 85-154-5, 7.5 85-154-6, 8.0 85-154-7, 8.5 85-154-8, 9.0
Brand Name	: Maxitex Neuro
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)	: 2777/10572-04/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, Ridlerstraβe 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

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.

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 21420:2020, EN ISO 374-1:2016+A1:2018/Type B, EN 374-2:2014, EN 16523-1:2015, EN ISO 374-4:2019, EN ISO 374-5:2016 (protecting against virus, bacteria and fungi), EN421:2010 (excluding clause 4.3).

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 ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2.	EN 455-1:2020+1:2022	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	February 2022
3.	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
4.	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
5.	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
6.	EN ISO14971:2019+A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	December 2021
7.	ISO 2859-1:2011	Sampling procedures and table for inspection by attributes	June 2011
8.	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products Microbiological methods - Part 1: Determination of a population of microorganisms on products - Amendment 1 (ISO 11737-1:2018/Amd 1:2021)	June 2021
9.	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10.	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices - Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006/Amd 2:2018)	November 2019
11.	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015
12.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020

13.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
14.	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
17.	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
18.	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
19.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
20.	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
21.	MEDDEV 2.4/1	2.4/1 Classification of Medical Device	Revision 9, June 2010
22.	MEDDEV 2.5/10	2.5/10 Guideline for Authorized Representative	January 2012
23.	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
24.	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013

EU DOC Issuance Date : 30th June 2023

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