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

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
Classification	: Class IIa
Brand	: Nuzone X2e
Conformity Assessment Procedure	: Annex II excluding 4

We herewith declare with our own responsibility that above mentioned product(s) with CE mark 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).

EC Certificate(s)	: G1 061155 0014 Rev. 02
EC Certificate(s) valid from	: 19th February 2021
EC Certificate(s) valid until	: 26th May 2024
Notified Body	: TÜV SÜD Product Service GmbH, Ridlerstraβe 65, 80339, Munich, Germany.
CE Number	: CE 0123
DoC Validity	: 11th November 2021 until 10th November 2022

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
RA/DOC/R3/026/11/21/03/LSPF/MB

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European Authorized Representative	: Ulma International GmbH Pfaffenweg 35, 89231 Neu-Ulm, Germany.
Name of Device	: Sterile Latex Surgical Gloves
Type	: Powdered
Classification	: Class IIa
Brand	: Maxitex
Conformity Assessment Procedure	: Annex II excluding 4

We herewith declare with our own responsibility that above mentioned product(s) with CE mark 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).

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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
Classification	: Class IIa
Brand	: Sensiflex Plus
Conformity Assessment Procedure	: Annex II excluding 4

We herewith declare with our own responsibility that above mentioned product(s) with CE mark 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).

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