



**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

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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 : Polychloroprene Surgical Gloves
Type : Powder Free
Brand : NUZONE X2E
Classification : Class IIa
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,
Ridlerstraße 65,
80339, Munich, Germany.

CE Number : CE 0123

DoC Validity : 8th October 2021 until 7th October 2022


Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
RA/DO/R3/019/10/21/07/CSPF/M



**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

DP 21/01/20/TGT