



**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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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 Darul Naim, Malaysia.

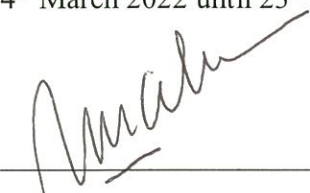
Name of Device : Sterile Nitrile Examination Gloves
Type : Powder Free
Classification : PPE Category III

I, the undersigned, hereby declare that the disposable device(s) specified above are following 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, EN420:2003+A1:2009, EN374-2:2014, EN374-4:2013 and EN374-5:2016.

Issued by : SATRA Technology Europe Ltd,
Bracetown Business Park,
Clonee, DIS YN2P,
Ireland.

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 Ltd, Bracetown Business Park, Clonee, DIS YN2P, Ireland is identical to the PPE EU Certificate of Conformity No: **2777/10580-02/E00-00.**

DoC Validity : 24th March 2022 until 23rd March 2023



Noor Akilah Bt Saidin
General Manager, RA
RA/DOC/PPER/R3/021/03/22/04/NPFS/M

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

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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.

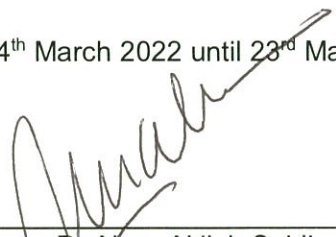
Name of Device : Sterile Nitrile Examination Gloves
Type : Powder Free
Classification : Class Is
Conformity Assessment Procedure : Annex V

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) : G2S 061155 0015 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 : CE0123

DoC Validity : 24th March 2022 until 23rd March 2023


Name: Ph Noor Akilah Saidin
Designation: General Manager, RA
RA/DOC/R3/074/03/22/03/NPFS/M