

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

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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.

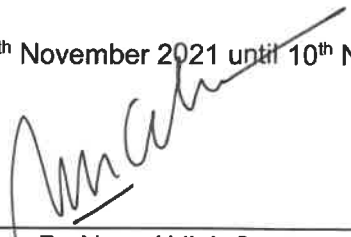
Name of Device : Sterile Latex Surgical Gloves  
Type : Powder Free  
Classification : Class IIa  
Brand : Nuzone X2e  
Conformity Assessment Procedure : Annex II excluding 4

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 14<sup>th</sup> 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 : 19<sup>th</sup> February 2021  
EC Certificate(s) valid until : 26<sup>th</sup> May 2024  
Notified Body : TÜV SÜD Product Service GmbH,  
Ridlerstraße 65,  
80339, Munich, Germany.

CE Number : CE 0123

DoC Validity : 11<sup>th</sup> November 2021 until 10<sup>th</sup> November 2022

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

*In #1*  
*Ken*

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



**TERANG NUSA (MALAYSIA)**  
**SDN. BHD.**  
**GOOD HEALTH, SAFETY FIRST & BE HONEST**

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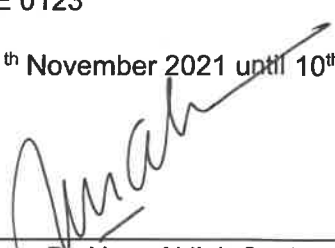
Name of Device : Sterile Latex Surgical Gloves  
Type : Powdered  
Classification : Class IIa  
Brand : Maxitex  
Conformity Assessment Procedure : Annex II excluding 4

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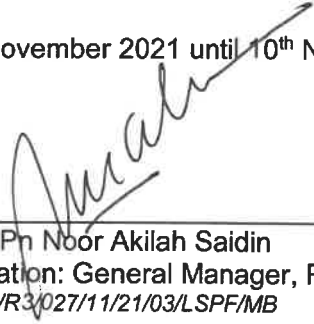
Name of Device : Sterile Latex Surgical Gloves  
Type : Powder Free  
Classification : Class IIa  
Brand : Sensiflex Plus  
Conformity Assessment Procedure : Annex II excluding 4

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 14<sup>th</sup> 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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