

A member of Top Glove Group: The World's Largest Manufacturer of Gloves

1, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan D.N., Malaysia.

+603 7890 3336/+609 774 7171 +609 771 3565/3072 +6012 2896 270 sales@topglove.com.my www.topglove.com

### DECLARATION OF CONFORMITY

Manufacturing Site : TERANG NUSA SDN. BHD.  
1, Jalan 8, Pengkalan Chepa 2,  
Industrial Zone,  
16100 Kota Bharu, Kelantan,  
Malaysia.

European Authorized Representative : Ulma International GmbH  
Pfaffenweg 35,  
89231 Neu-Ulm,  
Germany.

Customer : VULKAN MEDICAL

Brand : NUZONE X2E (FILM-FILM LARGE COMPACT)

PO No. : 202000159

Name of Device : CHLOROPRENE SURGICAL POWDER FREE  
POLYMER (Palm Textured/Embossed Outside, Tan)

Size	Lot No.	Quantity (prs)
6.0	236002631QLZA	600
6.5	236002631QLZA	5,000
7.0	236002631QLZA	8,000
7.5	236002631QLZA	3,000
8.5	236002631QLZA	600

Expiry Date : 2026-01

Manufacturing Date : 2021-02

Year of Manufacture : 2021

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 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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EC Certificate(s)	: G1 061155 0014 Rev. 01
EC Certificate(s) valid until	: 26th May 2024
Start of CE Marking and MDD Compliance	: 29th July 1997
Notified Body	: TÜV SÜD Product Service GmbH, RidlerstraBe 65, 80339, Munich, Germany.
CE Number	: CE 0123
DoC Issuance Date	: 09 <sup>th</sup> March 2021
DoC Expiry Date	: 26 <sup>th</sup> May 2024



Name: Rahayu Binti Mat Zin  
Designation: Snr. Manager, QA