

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 : DONA SENSITIVE (FILM-FILM LARGE COMPACT)

PO No. : 202000159

Name of Device : LATEX SURGICAL POWDERED GLOVE (Palm
Textured/Embossed Outside,Natural)

Size	Lot No.	Quantity (pcs)
6.0	236002631SPZA	8,000
6.5	236002631SPZA	20,000
7.0	236002631SPZA	40,000
7.5	236002631SPZA	28,000
8.0	236002631SPZA	20,000
8.5	236002631SPZA	6,000
9.0	236002631SPZA	3,000

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 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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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, Ridlerstraße 65, 80339, Munich, Germany.
CE Number	: CE 0123
DoC Issuance Date	: 11 th March 2021
DoC Expiry Date	: 26 th May 2024



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