TERANG NUSA SDN. BHD.
GOOD HEALTH, SAFETY FIRST & BE HONEST

Company No.
198701005830 (164501-X)

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.

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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 SENSI PLUS (FILM-FILM LARGE COMPACT)
PO No.	:	202000159
Name of Device	:	LATEX SURGICAL POWDER FREE POLYMER GLOVE (Palm Textured/Embossed Outside,Natural)

Size	Lot No.	Quantity (pcs)
6.0	236002631SLZA	25,000
6.5	236002631SLZA	50,000
7.0	236002631SLZA	50,000
7.5	236002631SLZA	40,000
8.0	236002631SLZA	30,000
8.5	236002631SLZA	5,000

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).

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   :10th March 2021
DoC Expiry Date   :26th May 2024

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