GOOD HEALTH, SAFETY FIRST & BE HONEST

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 \( \bar{\mathbf{l}} +609 771 3565/3072 \) \( \bar{\mathbf{l}} +6012 2896 270 \)** 

sales@topglove.com.my

www.topglove.com

## **DECLARATION OF CONFORMITY**

TERANG NUSA SDN. BHD. Manufacturing Site

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.

**VULKAN MEDICAL** Customer

**Brand** MAXITEX NEURO (FILM-FILM LARGE COMPACT)

PO No. 202000159

LATEX SURGICAL POWDER FREE POLYMER Name of Device

GLOVE (Palm Textured/Embossed Outside, Brown)

Size	Lot No.	Quantity (pcs)
6.0	236002631SLZA	1,000
6.5	236002631SLZA	6,000
7.0	236002631SLZA	6,000
7.5	236002631SLZA	4,000
8.0	236002631SLZA	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)

EC Certificate(s) valid until

Start of CE Marking and MDD Compliance

**Notified Body** 

: G1 061155 0014 Rev. 01

: 26th May 2024

: 29th July 1997

: TÜV SÜD Product Service GmbH,

RidlerstraBe 65.

80339, Munich, Germany.

**CE Number** 

**DoC Issuance Date DoC Expiry Date** 

: CE 0123

:09th March 2021 :26th May 2024

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