TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

TOP GLOVE SDN. BHD.
The World's Largest Manufacturer of Gloves
GOOD HEALTH, SAFETY FIRST & BE HONEST

Registration No.
199101010171 (220483-T)
SST ID: B16-1808-22000008

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.
+603 3392 1992 +603 3392 1291/8410 +6012 2896 270 sales@topglove.com.my www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES : 47 Factories (Malaysia, Thailand, Vietnam & China), 750 Production Lines, 90 Billion Gloves Per Annum, 21,000 Employees.
MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturing Site	: TOP GLOVE SDN. BHD : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang Selangor D.E., Malaysia.
Single Registration Number (SRN)	: MY-MF-000009690
European Authorized Representative	: Top Glove Europe GmbH Bliersheimer Str. 80A 47229 Duisburg ,Germany Tel.: +49-(0)2065-76421-0, Fax: +49-(0)2065-76421-19
Single Registration Number (SRN)	: DE-AR-000004968
Name of Device	: Latex Examination Polymer Powder Free
Product Code	: LPPS
Classification (MDR)	: Class I
Classification (PPER)	: Category III
Rule (MDR)	: Rule 5
Conformity Assessment Procedure (MDR)	: Annex I, Annex II and Annex IV (Self declared)
Conformity Assessment Procedure (PPER)	: Annex VII (Module C2)
Applicable Standards (MDR)	: Attachment I
Product Reference (PPER)	: EA301
EU Type Examination Certificate Number (PPER)	: 2777/10906-04/E00-00
EU Type Examination Certificate Issued by (PPER)	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
Notified Body Number (PPER)	: 2777
Intended use (MDR)	: The gloves are intended to be worn on the hand of healthcare personnel during medical examination procedures to protect cross-contamination between healthcare personnel and patient.

We Top Glove Sdn Bhd herewith declare with our own responsibility that the abovementioned product;

i. is fully compliance with the General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by TUV SUD Product Service GmbH. All supporting documentations are retained under the premise of manufacturer.

ii. is following to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 (EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019) and EN ISO 374-5:2016.

iii. is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

Basic UDI – DI (MDR) : 955760100560GG

DoC Issuance Date : 23th November 2023 until 22nd November 2024

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Place: Klang, Malaysia.
Date: 23th November 2023