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 6317 +603 3392 6348 +6012 2896 270 sales@topglove.com.my www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES : 50 Factories (Malaysia, Thailand, Vietnam & China), 812 Production Lines, 100 Billion Gloves Per Annum, 22,000 Employees.
MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

EU IZJAVA O SKLADNOSTI

Mesto proizvodnje: : TOP GLOVE SDN. BHD.
Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru,
41050 Klang, Selangor D.E., Malaysia.

Pooblaščeni predstavnik v EU: Top Glove Europe GmbH
Bliersheimer Str. 80 A,
47229 Duisburg, Germany

Ime : Nitril pregledne rokavice
Tip : Brez pudra
Klasifikacija : OVO Kategorija III
Referenca : EB201

Spodaj podpisani izjavljam, da zgoraj navedeni pripomočki za enkratno uporabo ustrezajo EU pregledu tipa in so skladni z določbami uredbe o osebni zaščitni opremi (EU) 2016/425 kategorije III in, kjer je tako, z nacionalnim standardom, ki prenaša usklajeni standard št. 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.

Izdano s strani: : SATRA Technology Europe Ltd,
Bracetown Business Park,
Clonee, DIS YN2P,
Ireland.

Za osebno varovalno opremo kategorije III velja postopek ugotavljanja skladnost s tipom na podlagi notranjega nadzora proizvodnje in nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih (modul C2) pod nadzorom priglašenega organa Satra Technology Europe Ltd Bracetown Business Park, Clonee, Dublin 15, Dublin št. 2777, ki je izdal certifikat o EU-pregledu tipa št**:** 2777/10648-07/E00-00.

Veljavnost dokumenta: : 16/62025 do 15/6/2027

Podpisano za in v imenu:
Noor Akilah Bt Saidin
Generalni direktor, RA
RA/DOCPPE/R3/006/06/25/10/NPF/M

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EU DECLARATION OF CONFORMITY (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
Single Registration Number (SRN)	: DE-AR-000004968
Name of Device	: Nitrile Examination Gloves
Type of Product	: Powder Free
Product Code	: NPFN
Classification	: Class I
Rule	: Rule 5
Conformity Assessment Procedure	: Annex II, Annex III, and Annex IV (Self declared)
Brand Name, Catalogue Number, and Sizes	: Attachment I
Applicable Standards	: Attachment II
Intended use	: 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.

This declaration of conformity is issued under the sole responsibility of Top Glove Sdn. Bhd. We hereby declare that the medical device (s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by TÜV SÜD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

Basic UDI-DI	: 955760101940H5
DoC Validity Date	: 13th June 2025 to 12th June 2027

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Place: Klang, Malaysia.
Date: 13th June, 2025

ATTACHMENT I

No.	Brand / Sizes	Catalogue Number (CN)			
		S	M	L	XL
1.	IDEAL-T	132 112S	132 113S	132 114S	132 115S

ATTACHMENT II

Applicable Standards:

No	Standard	Descriptions	Date Published
1.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2.	EN 455-1:2020+A2:2024	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	September 2024
3.	EN 455-2:2024	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	May 2024
4.	EN 455-3:2023	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation	December 2023
5.	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
6.	EN ISO14971:2019+A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	December 2021
7.	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8.	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
9.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
10.	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	February 2023
11.	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
12.	EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	May 2020

No	Standard	Descriptions	Date Published
13.	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
14.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
15.	EN 62366-1:2015/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
16.	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
17.	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
18.	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
19.	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
20.	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
21.	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
22.	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
23.	MEDDEV 2.7/1	Clinical Evaluation	Revision 4, June 2016
24.	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
25.	MEDDEV 2.12/1	Medical Device Vigilance System	Revision 8, January 2013
26.	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
27.	MEDDEV 2.12/2	Post Market Clinical Follow-up Studies	Revision 2, January 2012