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 IZJAVA O SKLADNOSTI

Ime pripomočka: Nitril pregledne rokavice brez pudra

Ime znamke:: IDEAL-T

Kataloške številke in velikosti blagovne znamke navedene v

prilogi I

Mesto proizvodnje:

TOP GLOVE SDN. BHD

Lot 4969, Jalan Teratai, Batu 6,

Off Jalan Meru, 41050 Klang Selangor D.E.,

Malaysia.

MDR 2017/745

Enotna registracijska številka	: MY-MF-000009690
Pooblaščeni predstavnik v EU:	: Ulma International GmbH Alfred-Nobel-Straße 5 50226 Frechen, Germany.
Enotna registracijska številka	: DE-AR-000010015
Pravilo razvrščanja	: Rule 5, Class 1
Postopek ugotavljanja skladnosti	: Annex II, Annex III, and Annex IV
Osnovni UDI – DI	: 955760101940H5
Veljavni standardi	: Priloga II

Namen uporabe: Rokavice so namenjene nošenju na rokah zdravstvenega osebja med zdravniškimi pregledi za zaščito pred navzkrižno kontaminacijo med zdravstvenim osebjem in pacientom.

PPE 2016/425

Referenca pripomočka	: EB201
Klasifikacija	: Kategorija III
Postopek ugotavljanja skladnosti	: Annex V (Modul B) and Annex VII (Modul C2) :
Certifikat o EU-pregledu tipa	2777/10648-07/E00-00
Priglašen organ za ugotavljanje skladnosti	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
CE	:CE 2777

Namen uporabe: Rokavice so namenjene nošenju na rokah zdravstvenega osebja med zdravniškimi pregledi za zaščito pred navzkrižno kontaminacijo med zdravstvenim osebjem in pacienti.

Zaključek:

Družba Top Glove Sdn Bhd s tem na lastno odgovornost izjavlja, da je zgoraj navedeni izdelek z oznako CE;

I. Izpolnjujejo določbe Uredbe (EU) MDR 2017/745 za medicinske pripomočke. To izjavo podpira tudi odobritev sistema vodenja kakovosti po standardu ISO 13485, ki jo je izdal TUV SUD Product Service GmbH. Vsa podporna dokumentacija se hrani v prostorih proizvajalca.

IIa. Izpolnjujejo zahteve EU za tipski pregled in so skladni z določbami nove uredbe o osebni varovalni opremi (EU) 2016/425 kategorije III, Priloga V (modul B) 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), EN ISO 374-5:2016, EN ISO 374-5:2016 in EN 421:2010 (razen točke 4.3).

IIb. Za izdelek veljajo postopki iz Priloge VII (Modul C2) uredbe o osebni varovalni opremi (EU) 2016/425 pod nadzorom priglašenega organa. SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

Veljavnost 19/1//2026 do 18/1/2028

Podpisano za in v imenu:
Noor Akilah Saidin Designation:
Direktor, RA
Datum: 19. Januar 2026

ATTACHMENT I: CATALOGUE NUMBER OF RESPECTIVE BRAND

	Brand / Size	CATALOGUE NUMBER			
		S	M	L	XL
1.	IDEAL-T	332312S	332313S	332314S	332315S

ATTACHMENT II: LIST OF APPLICABLE STANDARDS AND REFERENCE FOR MDR 2017/745

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

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No	Standard	Descriptions	Date Published
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 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	November 2021
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
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/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 D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems	February 2022
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

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No	Standard	Descriptions	Date Published
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