

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Latexové rukavice LATEX^{BLUE}

ČÁST I: POPIS PRODUKTU

| | |
|-------------|--|
| Typ: | jednorázové nesterilní ochranné rukavice |
| Materiál: | přírodní latex s vysokým stupněm kvality |
| Barva: | modrá |
| Provedení: | pravolevé, zdrsňené konečky prstů, koráلكová manžeta |
| Pudr: | není přidán |
| Skladování: | rukavice neztrácejí své vlastnosti při skladování v suchu při teplotě od 10 do 30 °C |
| Životnost: | 5 let od data výroby při dodržení podmínek skladování |
| Balení: | 100 ks v krabičce, 10 krabiček v kartonu |

ČÁST II: SPECIFIKACE PRODUKTU

| | |
|-------------------------------|---|
| Délka (mm): | min. 240 |
| Šířka (mm): | XS – 76 ± 3 S – 84 ± 3 M – 94 ± 3 L – 105 ± 3 XL – 113 ± 3 |
| Tloušťka (mm): | prsty: 0.11 ± 0.02 (typická hodnota 0.11 – 0.13) dlaň: 0.10 ± 0.02 (typická hodnota 0.10 – 0.11) |
| Prodloužení do přetržení (%): | min. 650 (typická hodnota 650 – 750) |
| Pevnost v tahu (MPa): | min. 18 (typická hodnota 18 -20) |
| AQL: | 1.5 |



ČÁST III: NORMY A NAŘÍZENÍ

Tímto potvrzujeme, že výše uvedený výrobek je v souladu s:

Obecné: PPER (EU) 2016/425 Cat. I
EN 420

Potravinářství: EC 1935/2004
EC 2023/2006
EU 10/2011 * Vyhovuje pro všechny simulanty kromě 3% kyseliny octové. Tento produkt je vhodný pro manipulaci s potravinami, kromě kyselých potravin (testováno 2 hodiny při 40 ° C)

ČÁST IV: POLOŽKY

| Pol. č. | Velikost | Hmotnost (g) | Rozměry (mm) | Kvalita (g) | EAN |
|---------|----------|--------------|--------------|-------------|---------------|
| 100122 | S | 500 | 215×120×70 | 4.8 ± 0.2 | 8594177201190 |
| 100123 | M | 550 | 215×120×70 | 5.3 ± 0.2 | 8594177201206 |
| 100124 | L | 600 | 215×120×70 | 5.8 ± 0.2 | 8594177201213 |
| 100125 | XL | 650 | 215×120×70 | 6.2 ± 0.2 | 8594177201220 |

ČÁST V: NÁHLED PRODUKTU





ČÁST VI: PŮVOD PRODUKTU

Výrobce:

Top Glove Sdn Bhd, No 16, Persiaran Setia Dagang, Setia Alam, Seksyen U13, 40170 Shah Alam, Selangor, Malaysia

Distributor:

Espeon s.r.o., U větrolamu 1212/53, 184 00 Praha 8, info@espeon.cz , www.espeon.cz



TOP GLOVE **TOP GLOVE SDN. BHD.** (Company No. 220483-T)
TOP QUALITY, TOP EFFICIENCY **The World's Largest Manufacturer of Gloves** (SST ID: B16-1808-22000008)
GOOD HEALTH, SAFETY FIRST & BE HONEST

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 📠 +6012 2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 63.9 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

EU DECLARATION OF CONFORMITY (EU DoC)

Manufacturer's Name : TOP GLOVE SDN. BHD
Manufacturer's Address : Lot 4969, Jalan Teratai, Batu 6,
Off Jalan Meru, 41050 Klang,
Selangor D.E., Malaysia.
Single Registration Number (SRN) : TBA
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) : TBA
Name of Device : Latex Examination Gloves
Type : Polymer Powder Free
Classification : Class I, Non Sterile
Brand Name : ESPEON
Size : XS, S, M, L, XL
Conformity Assessment Procedure : Annex I, Annex II and Annex IV (Self declared)
Rule : Rule 1 & Rule 5

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745 repealed by Council Directives 93/42/EEC. All supporting documentations are retained under the premise of manufacturer.

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

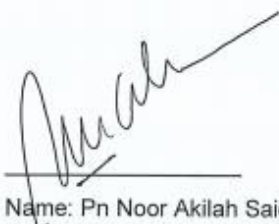
DP 260819/TGT

Applicable Standards:

| No | Standard | Descriptions | Date Published |
|----|--|---|----------------|
| 1 | EN 455-1:2000 | Medical gloves for single use. Part 1: Requirement and testing for freedom from holes. | October 2000 |
| 2 | EN 455-2:2015 | Medical gloves for single use. Part 2: Requirement and testing for physical properties. | April 2015 |
| 3 | EN 455-3:2015 | Medical gloves for single use. Part 3: Requirement and testing for biological evaluation. | April 2015 |
| 4 | EN 455-4:2009 | Medical gloves for single use. Part 4: Requirements and testing for shelf life determination. | October 2009 |
| 5 | EN ISO 14971:2012 | Medical device - Application of risk management to medical device. | July 2012 |
| 6 | 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 |
| 7 | ISO 10993-1:2018 | Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process | Aug 2018 |
| 8 | ISO 10993-5:2009 | Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity | June 2009 |
| 9 | EN ISO 10993-10:2013 | Biological evaluation of medical devices - Tests for irritation and skin sensitization. | Feb 2014 |
| 10 | EN ISO 10993-11:2018 | Biological evaluation of medical devices. Tests for systemic toxicity | June 2018 |
| 11 | ISO 10993-12:2012 | Biological evaluation for medical devices - Sample preparation and reference materials | June 2012 |
| 12 | EN ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements. | Nov 2016 |
| 13 | MDR 2017/745 (Annex I: Chapter 2) | Requirements Regarding Design and Manufacture | April 2017 |
| 14 | MDR 2017/745 (Chapter I: Article 2) | Scope and Definitions | April 2017 |
| 15 | MDR 2017/745 (Annex VIII) | Classification rules | April 2017 |

| No | Standard | Descriptions | Date Published |
|----|--|---|-------------------------------|
| 16 | MDR 2017/745 (Annex II) | Technical Documentation | April 2017 |
| 17 | MDR 2017/745 (Chapter II: Article 11&12) | Guideline for Authorized Representative | April 2017 |
| 18 | MDR 2017/745 (Annex XIV: Part A) | Clinical Evaluation | April 2017 |
| 19 | MEDDEV 2.7/1 | 2.7/1 Clinical Evaluation | Revision 4, June 2016 |
| 20 | MEDDEV 2.12-1 rev 8 | Medical Device Vigilance System | January 2013 |
| 21 | MEDDEV 2.12/1 | 2.12/1 Medical Device Vigilance System | Revision 8, January 2013 |
| 22 | MDR 2017/745 (Chapter VII: Section 2: Article 87-92) | Vigilance | April 2017 |
| 23 | MDR 2017/745 (Annex XIV: Part B) | Post Market Clinical Follow-up Studies | April 2017 |
| 24 | MEDDEV 2.12/2 | 2.12/2 Post Market Clinical Follow-up Studies | Revision 2, January 2012 |
| 25 | MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III | Post Marketing Surveillance (PMS) | April 2017 |
| 26 | MEDDEV 2.12/Rec 1 | 2.12 Post - Marketing Surveillance (PMS) post market / production | Revision 11, February 2000 |
| 27 | MDR 2017/745 | Medical Device Regulation | April 2017 |

Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.
Registration Date : 31 March 2010
Registration No : DE/CA20/02-TOPGLOVEB-01/10
EU DoC Issuance Date : 7th July 2020
EU DoC Expiry Date : 7th July 2023
Basic UDI – DI : 955100429010B8

A handwritten signature in black ink, appearing to read "Pn Noor Akilah Saidin", written over a horizontal line.

Name: Pn Noor Akilah Saidin
Designation: RA Deputy General Manager



TOP GLOVE **TOP GLOVE SDN. BHD.** (Company No. 220483-T)
(GST ID: 000662692096)
TOP QUALITY, TOP EFFICIENCY **The World's Largest Rubber Glove Manufacturer**
GOOD HEALTH, SAFETY FIRST & BE HONEST

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FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050, Klang, Selangor D.E., Malaysia.
☎ +603-3392 4211 📠 +603-3392 4200 📞 +6012-2696 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 34 Factories (Malaysia, Thailand & China), 581 Production Lines, 55.8 Billion Gloves Per Annum, 12,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA and Germany.

Date: 27th May, 2019

To: Whom It May Concern

RE : LETTER OF DECLARATION

This is to certify that our production of Latex Powder Free Gloves are complying with the EU Food regulation 1935/2004 and 2023/2006, tested according to requirement of the Plastic Material and Articles in contact with food commission follow the new regulation (EU) No. 10/2011 of 14 January, 2011

We also confirm that our Latex Powder Free Gloves are suitable for food handling but not for Acetic Acid.

Verified by,

Pn. Noor Akilah Bte Saidin
Deputy General Manager, RA

RA/LOD/012/05/2019

"To Prevent and Reduce Corruption and Bribery", "Be Honest and No Cheating"



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+603 3392 1992 +603 3392 1291 +6012 2696 270 sales@topglove.com.my www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 63.9 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

Date : 7th July, 2020

To : Whom it May Concern

SUB: LETTER OF DECLARATION

We, Top Glove Sdn Bhd declare that our Latex Polymer Powder Free Gloves complies with EU Food regulation 1935/2004 and 2023/2006 and tested according to requirements of the Plastic Materials and Articles in contact with food commission follow the new Regulation (EU) No. 10/2011 of 14 January, 2011 (published on 14th September 2018 and incorporating 11 amendments) except for 3% acetic acid.

Verified by:

Pn. Noor Akilah Bt Saidin
Deputy General Manager, RA
RA/LOD/001/07/2020

#ad

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