PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Latexové rukavice LATEX MEDICAL 3

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné a vyšetřovací rukavice
Materiál:	přírodní latex s vysokým stupněm kvality
Barva:	přírodní bílá
Provedení:	pravolevé, zdrsněné konečky prstů, korálková 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: 0.12 ± 0.02 (typická hodnota 0.11 – 0.13) dlaň: 0.11 ± 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. III CE2777 EN 420:2003+A1:2009 EN ISO 374-1:2016 EN ISO 374-1:2016/TYPE B EN ISO 374-4:2013 EN ISO 374-5:2016
Zdravotnictví:	EN 455 MDR(EU) 2017/745
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
100030	XS	530	225x125x75	4.6 ± 0.2	9551004290122
100012	S	532	225x125x75	5.1 ± 0.2	9551004290139
100013	M	579	225x125x75	5.6 ± 0.2	9551004290146
100014	L	634	225x125x75	6.1 ± 0.2	9551004290153
100015	XL	753	225x125x75	6.6 ± 0.2	9551004290160

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

ESPEON

TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

TOP GLOVE SDN. BHD. (Company No. 220483-T)
(SST ID: B16-1808-22000008)
The World's Largest Manufacturer of Gloves
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

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

TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

TOP GLOVE SDN. BHD. (Company No. 220483-T)
(GST ID: 000562692096)
The World's Largest Rubber Glove Manufacturer
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 4211 +603-3392 4200 +6012-2896 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

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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

SATRA TECHNOLOGY

Issued to:

Top Glove Sdn Bhd
Lot 4969 Jalan Teratai
Batu 6
Off Jalan Meru
41050 KLANG
Selangor D E
Malaysia

Notified Body: 2777

SATRA customer number: P0130

EU Type-Examination Certificate

Certificate number: 2777/10906-03/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

EA301

Description:

Latex examination polymer powder free glove available in Natural Colour, Black and Dark Blue.

Sizes:

6	XS
7	S
8	M
9	L
10	XL

Classification:

EN ISO 374-1:2016/Type B	**Level**	**EN 374-4:2013**
40% Sodium Hydroxide (K)	6	-43.5%
65% Nitric Acid (M)	1	57.0%
37% Formaldehyde (T)	3	-28.3%
30% Hydrogen Peroxide (P)	1	-1.9%
40% Hydrofluoric Acid (S)	3	Not Tested

EN ISO 374-5:2016	
Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0229275/1443 Issue 5, SPC0229275/1443/SMcD-Final-Issue 3, SPC0234310/1518/1 Issue 3, CHM0266051/1802/LC/A, CHM0266051/1802/LC/B, CHM0266051/1802/LC/C, CHM0266051/1802/SPT, CHM0276738/1841/JH/B/Issue 2, SPC0276572/1841, CHM0276738/1841/JH/C-Issue 2, CHM0279961/1902/JG/A, CHM0279961/1902/JG/B
TUV: 7191118865-CHM15-03A-RC_CR1

Signed on behalf of SATRA: Hannah Coe Geoff Graham

Date first issued: 19/07/2018
Date of issue: 22/03/2019

Expiry date: 19/07/2023