

## PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

### Nitrilové rukavice NITRIL<sup>COMFORT</sup>

#### ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné a vyšetřovací rukavice
Materiál:	100% syntetický nitril
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: 0.10 ± 0.02 (typická hodnota 0.08 – 0.11) dlaň: 0.07 ± 0.02 (typická hodnota 0.06 – 0.08)
Prodloužení do přetržení (%):	min. 500
Pevnost v tahu (MPa):	min. 6
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

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
100029	XS	369	200×110×60	3.2 ± 0.2	9551004290221
100006	S	424	200×110×60	3.5 ± 0.2	9551004290238
100007	M	440	200×110×60	3.8 ± 0.2	9551004290245
100008	L	480	200×110×60	4.1 ± 0.2	9551004290252
100011	XL	520	200×110×60	4.4 ± 0.2	9551004290269

#### 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](mailto:info@espeon.cz) , [www.espeon.cz](http://www.espeon.cz)



**TOP GLOVE**  
TOP QUALITY, TOP EFFICIENCY

**TOP GLOVE SDN. BHD.** (Company No. 220483-T)  
**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 : Nitrile Examination Gloves  
Type : 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.

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BE HONEST AND NO CHEATING"**

DP 260819/TGT

Fal.

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 : 7<sup>th</sup> July 2020  
EU DoC Expiry Date : 7<sup>th</sup> July 2023  
Basic UDI – DI : 955100429020BB



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





AWARDED  
ISO 9001

**TOP GLOVE SDN. BHD.** (Company No. 220483-T)  
**TOP QUALITY, TOP EFFICIENCY,  
GOOD HEALTH, SAFETY FIRST & BE HONEST**

\* A member of Top Glove Corporation Bhd, Public Listed Company on Bursa Malaysia.  
Latex Examination, Nitrile, Surgical, Vinyl & Household Gloves Manufacturer and Exporter  
The World's Largest Rubber Glove Manufacturer

Corporate Office : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D. E., Malaysia.  
& Factory 9 Tel: 603-3392 1992 / 1905 Fax: 603-3392 8410 / 1291  
E-mail : sales@topglove.com.my Website : www.topglove.com.my



1998 to 2007  
Celebrating Malaysia's  
Enterprising Spirit

<b>BUSINESS DIRECTION</b>	: To Produce Consistently High Quality Gloves At Efficient Low Cost.
<b>FACILITIES</b>	: 26 Factories (Malaysia, Thailand & China), 487 Production Lines, 45 Billion Gloves Per Annum, 11,000 Employees
<b>MARKET</b>	: Exports to more than 185 countries worldwide with Marketing offices in the USA and Germany.

Date: 8<sup>th</sup> May 2014

To: Whom It May Concern

**Subject: LETTER OF DECLARATION**

This is to certify that our production of Nitrile Examination Powdered and Powder Free Gloves comply 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.

We also confirm that our Nitrile gloves are suitable for food handling but not for Acetic Acid.

Verified by

Pn Noor Akilah Saidin  
QA Deputy General Manager

RA/LOD/033/04/14-1



GERMANY



EUROPE



U.S.A.



AUSTRALIA



CANADA



MALAYSIA

**"To Prevent & Against Corruption" and "Be Honest, No Cheating"**





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(GST ID: 000562692096)  
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**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.

## DECLARATION OF CONFORMITY

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

European Authorized Representative : Top Glove Europe GmbH  
Bliersheimer Str. 80, D-47229 Duisburg  
Deutschland/Germany  
Tel.: +49-(0)2065-76421-0,  
Fax: +49-(0)2065-76421-19

Name of Device : Nitrile Examination Gloves  
Type : Powder Free  
Classification : Class I  
Conformity Assessment Procedure : Annex VII  
Conformity Route : Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14<sup>th</sup> June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Competent Authority : Bezirksregierung Düsseldorf,  
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010  
Registration No : DE/CA20/02-TOPGLOVEB-01/10

Date : 2<sup>nd</sup> October 2019

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

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DP 080518/TGT