

PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST

Nitrilové rukavice NITRIL PREMIUM 3

ČÁST I: POPIS PRODUKTU

| | |
|-------------|--|
| Typ: | jednorázové nesterilní ochranné a vyšetřovací rukavice |
| Materiál: | 100% syntetický nitril |
| Barva: | fialová |
| 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 0.10 – 0.12) dlaň: 0.075 ± 0.02 (typická hodnota 0.07 – 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. 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 |
|---------|----------|--------------|--------------|-------------|---------------|
| 100050 | S | 429 | 200×110×60 | 3.7 ± 0.2 | 9551004290733 |
| 100051 | M | 460 | 200×110×60 | 4.0 ± 0.2 | 9551004290740 |
| 100052 | L | 500 | 200×110×60 | 4.3 ± 0.2 | 9551004290757 |
| 100053 | XL | 540 | 200×110×60 | 4.6 ± 0.2 | 9551004290764 |

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 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 | : Nitrile Examination Gloves |
| Type | : Powder Free |
| Classification | : Class I, Non Sterile |
| Brand Name | : ESPEON |
| Size | : XS, S, M, L, XL |
| Conformity Assessment Procedure Rule | : Annex I, Annex II and Annex IV (Self declared) : 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 : 7th July 2020
EU DoC Expiry Date : 7th 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

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

Date: 8th 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"



TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

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(GST ID: 000562692096)
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☎ +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 : 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

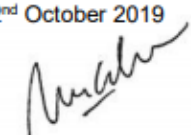
Name of Device : Nitrile Examination Gloves
Type : Powder Free
Classification : Class I
Conformity Assessment Procedure : Annex VII
Conformity Route : Self Declaration

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 14th 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 : 2nd October 2019


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

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DP 080518/TGT