PROHLÁŠENÍ O SHODĚ A PRODUKTOVÝ LIST
Nitrilové rukavice NITRIL LONG

ČÁST I: POPIS PRODUKTU

Typ:	jednorázové nesterilní ochranné a vyšetřovací rukavice
Materiál:	100% syntetický nitril
Barva:	modrá
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. 300
Šířka (mm):	XS – 76 ± 3 S – 84 ± 3 M – 94 ± 3 L – 105 ± 3 XL – 113 ± 3
Tloušťka (mm):	prsty: 0.14 ± 0.02 (typická hodnota 0.13 – 0.15) dlaň: 0.10 ± 0.02 (typická hodnota 0.11 – 0.12)
Prodloužení do přetržení (%):	min. 500
Pevnost v tahu (MPa):	min. 14
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
100099	S	610	235x125x70	5.9 ± 0.2	9551004290832
100100	M	640	235x125x70	6.2 ± 0.2	9551004290849
100101	L	670	235x125x70	6.5 ± 0.2	9551004290856
100102	XL	700	235x125x70	6.8 ± 0.2	9551004290863

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	: 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.

"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	: 955100429020BB

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

ESPEON

TOP GLOVE SDN. BHD. (Company No. 220483-T)

TOP QUALITY, TOP EFFICIENCY,
GOOD HEALTH, SAFETY FIRST & BE HONEST

AWARDED ISO 9001

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

ENTREPRENEUR OF THE YEAR® MALAYSIA 2004 BY ERNST & YOUNG

Enterprise 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

TOP GLOVE
TOP QUALITY, TOP EFFICIENCY

TOP GLOVE SDN. BHD. (Company No. 220483-T) (GST ID: 000562692096)
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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 : 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