TOP GLOVE

TOP QUALITY, TOP EFFICIENCY

THE WORLD'S LARGEST MANUFACTURER OF GLOVES

NITRILE GLOVE

POWDERED & POWDER-FREE

Functional Benefits:

- Protection from unwanted or dangerous substances
- Beaded cuff makes donning easy and helps prevent roll back
- Superior strength with better puncture resistance
- Full textured enhances wet and dry grip
- Thinner gauger improves tactile sensitivity
- Custom design enhances comfort and fit
- Provide an alternative solution for individuals who are allergic to natural rubber latex

NITRILE GLOVE

POWDERED & POWDER-FREE

Quality Standards

- Conforms to ASTM D6319 and EN455 Standards
- Manufactured under QSR (GMP), ISO 9001:2015 and ISO 13485:2016 Quality Management System

Glove Sizes

- Extra-Small, Small, Medium, Large, Extra-Large
- Size of gloves shall be marked in the check box on the shipping carton with black ink

Product Specifications

Type : Powdered & Powder-Free, Non-sterile

Material : 100% Synthetic Nitrile Latex

Colour : Blue, White, Green, Pink, Light Purple, Black, Red

Design & Features : **Powdered:**
Ambidextrous, finger textured or palm textured surface, beaded cuff, USP grade absorbable cornstarch

Powder-Free:
Polymer coated or online single chlorinated, offline double chlorinated, ambidextrous, finger textured or palm textured surface, beaded cuff

Storage : The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight

Shelf-life : 5 years from the date of manufacturing

Physical Dimensions

Dimensions	Standards		
	Top Glove	ASTM D3578	EN 455
Length (mm)	Min 230, Min 240, 300 ± 10	Min 220 (XS, S) Min 230 (M, L, XL)	Min 240
Palm Width (mm)			
• XS	76 ± 3	70 ± 10	≤ 80
• S	84 ± 3	80 ± 10	80 ± 10
• M	94 ± 3	95 ± 10	95 ± 10
• L	105 ± 3	110 ± 10	110 ± 10
• XL	113 ± 3	120 ± 10	≥ 110
Thickness : Single Wall (mm)			
• Finger	Min 0.05	Min 0.05	N/A
• Palm	Min 0.05	Min 0.05	N/A

Physical Properties

Property	ASTM D6319	EN 455
Tensile Strength (MPa)		
• Before Aging	Min 14	N/A
• After Aging	Min 14	N/A
Elongation at Break (%)		
• Before Aging	Min 500	N/A
• After Aging	Min 400	N/A
Median Force at Break (N)		
• Before Aging	N/A	Min 6
• After Aging	N/A	Min 6

International Quality Certificate Awarded:

DP/300519/TGT

If you have any enquiries on our products, please contact :

TOP GLOVE SALES & CORPORATE OFFICE

Level 21, Top Glove Tower,
16, Persiaran Setia Dagang,
Setia Alam, Seksyen U13,
40170 Shah Alam,
Selangor D.E., Malaysia.

Tel : +603-3362 3098
Fax : +603-3362 5096 (Sales)
Email : sales@topglove.com.my

Top Glove Website

https://www.facebook.com/mytopglove

www.topglove.com

TOP GLOVE SDN. BHD.

PRODUCT SPECIFICATION
Nitrile Powder Free Examination Gloves (Palm Textured)

SECTION I: PRODUCT DESCRIPTION

1. 1	Type	Nitrile Examination Glove, Powder Free, Online Single Chlorinated, Non-sterile
1. 2	Material	100% Synthetic Nitrile Latex
1. 3	Color	Blue
1. 4	Design and Feature	Ambidextrous, palm textured, beaded cuff
1. 5	Powder	No powder lubricant added
1. 6	Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
1. 7	Shelf-Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 8	Packing Style	100 pcs gloves x 10 dispensers x 1 carton
1. 9	Size Marking	The size of gloves shall be marked in the check box on every carton with black ink.

SECTION II: PERFORMANCE REQUIREMENTS

(Sampling Plan – ISO 2859 Single Normal)

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D6319-10 (2015)
2.2	Physical Properties	S2	4.0	ASTM D6319-10 (2015)
2.3	Freedom from Holes (Air Pump Test)	GI	1.5	In-house practice
2.4 (i) (ii)	Visual Defects: Major Visual Minor Visual	GI	 2.5 4.0	In-house practice
2.5 (i) (ii) (iii)	Packaging Defects: Regulatory Visual Critical (incl. Gloves Counting)	 GI GI S2	 ** 4.0 4.0	In-house practice
2.6	Powder Free Residue	N=5	-	ASTM D6319-10 (2015) ASTM D6124-06 (2011)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

TOP GLOVE SDN. BHD.

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length (mm)	All Sizes	300 +/- 10
Palm Width (mm)	XS S M L XL XXL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3 123 +/- 3
Thickness (mm) *single wall	All Sizes	Finger : 0.15 +/- 0.02 (Typical value: 0.14 – 0.17) Palm : 0.14 +/- 0.02 (Typical value: 0.13 – 0.16)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break (%)	Min 500 (Typical value: 500 - 600)	Min 400 (Typical value: 400 - 550)
Tensile Strength (MPa)	Min 14 (Typical value: 14 - 20)	Min 14 (Typical value: 14 - 20)

3.3 Freedom from Holes

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects

The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects

The Sample size and allowable number of non-conforming in the samples for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements (Gloves Counting=100 pcs by weight per Dispenser).

3.6 Powder Free Residue

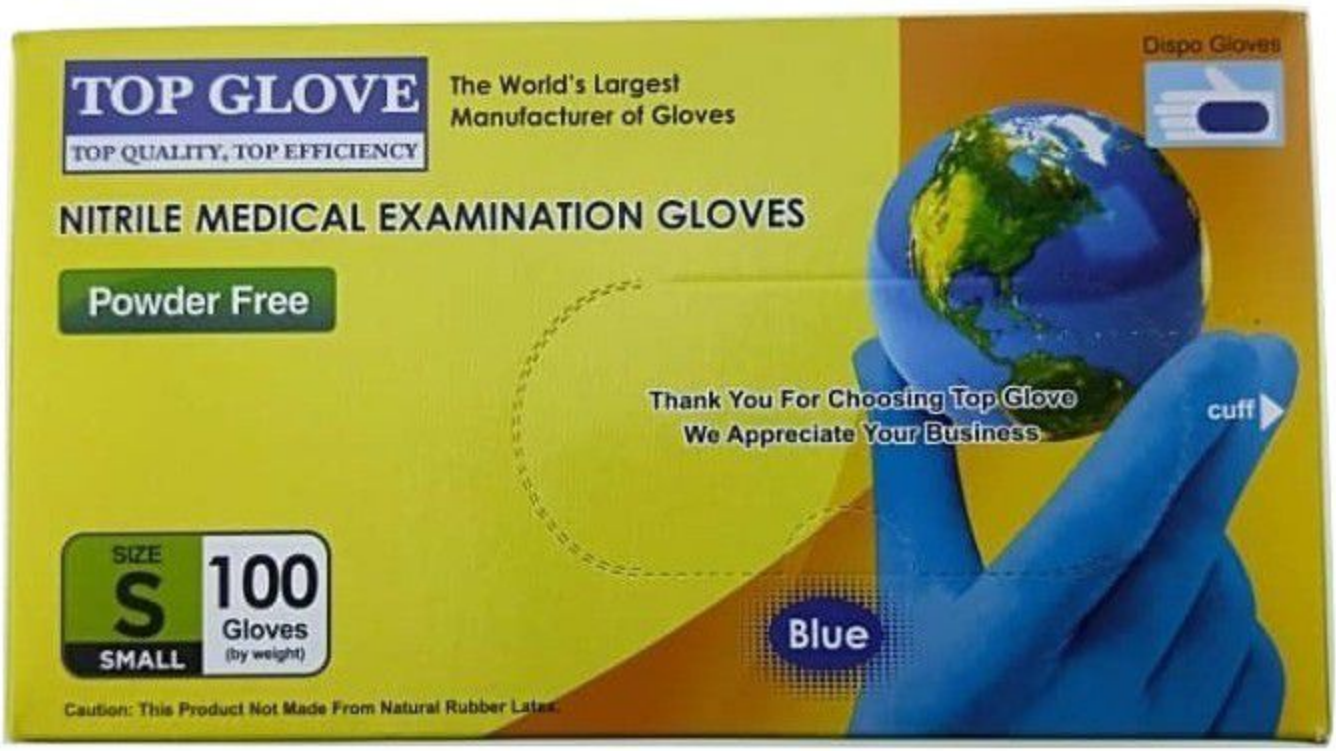
Maximum 2 mg per glove

Prepared by:
Quality Product Management System Division

Date: 17th May 2017

Checked by:
Eva Vinoni Bt Mustafa
Senior Manager, QA

Approved by:
Noor Akilah Saidin
Deputy General Manager, QA


TOP GLOVE
TOP QUALITY, TOP EFFICIENCY
The World's Largest Manufacturer of Gloves
Dispo Gloves
NITRILE MEDICAL EXAMINATION GLOVES
Powder Free
Thank You For Choosing Top Glove
We Appreciate Your Business
cuff
SIZE
S
SMALL
100
Gloves
(by weight)
Blue
Caution: This Product Not Made From Natural Rubber Latex.

TOP GLOVE

TOP QUALITY, TOP EFFICIENCY


TOP GLOVE
TOP QUALITY, TOP EFFICIENCY
The World's Largest Manufacturer of Gloves
NITRILE MEDICAL EXAMINATION GLOVES
Powder Free
Thank You For Choosing Top Glove
We Appreciate Your Business
OPEN HERE
SIZE
M
MEDIUM
50
Gloves
(by weight)
Blue
Caution: This Product Not Made From Natural Rubber Latex.

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 50 1998 to 2007 Celebrating Malaysia's Enterprising Spirit

BUSINESS DIRECTION	: To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES	: 27 Factories (Malaysia, Thailand & China), 485 Production Lines, 44 Billion Gloves Per Annum, 11,000 Employees
MARKET	: Exports to more than 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, 6th Mile, Off Jalan Meru, 41050 Klang, Selangor D. E. Malaysia
Authorized Representative	: EDQ Resources No 13 Jalan TS 6/4, Taman Industri Subang 47610 Subang Jaya, Selangor, Malaysia Tel.:+603-5035-9683, Fax:+603-5035-9688
Name of Device	: Examination Gloves
Type	: Powdered and Powder Free
Classification	: Class I, Non Sterile
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.

Registration Date	: 31 March 2019
Registration No	: DE/CA20/02-TOPGLOVEB-01/19
Date	: 1st December 2019

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

RA/DOC/A

No. Siri: 005751
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GMD26733243217A**
Registration No.:

Tarikh Sah Laku Pendaftaran: **25/08/2017 - 24/08/2022**
Registration Validity Date:

Sijil ini adalah dengan ini dikeluarkan kepada:
This Certificate is hereby issued to:

TOP GLOVE SDN BHD

yang beralamat di:
of:

LOT 4969, JALAN TERATAI, BATU 6,
OFF JALAN MERU,
KLANG
41050 SELANGOR

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

ZAMANE BIN ABDUL RAHMAN
Ketua Eksekutif
Chief Executive
Pihak Berkuasa Peranti Perubatan
Medical Device Authority

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GMD26733243217A**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan *Medical Device Name*	**NITRILE EXAMINATION POWDER FREE GLOVES**		
Kelas *Class*	**CLASS A**	Brand *Brand*	**TOP GLOVE**
Kelompok *Group*	**FAMILY**		
Kegunaan Yang Diniatkan *Intended Use*	**TO WEAR ON HANDS OF HEALTHCARE PERSONNEL TO PREVENT CONTAMINATION BETWEEN HEALTHCARE PERSONNEL AND THE PATIENT.**		
Nama dan alamat pembuat: *Name and address of manufacturer*	**LOT 4969, JALAN TERATAI, BATU 6, OFF JALAN MERU, KLANG 41050 SELANGOR**		

APPENDIX

No.	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-S	SINGLE USE GLOVES
2.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-XS	SINGLE USE GLOVES
3.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-M	SINGLE USE GLOVES
4.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-L	SINGLE USE GLOVES
5.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-XL	SINGLE USE GLOVES
6.	NITRILE EXAMINATION POWDER FREE GLOVES	N02-XXL	SINGLE USE GLOVES

MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH MALAYSIA

TOP GLOVE SDN BHD
TEST REPORT

Type Of Glove	:	**Nitrile Examination Chlorinated Powder Free Glove (Textured)**
Glove Code	:	**CW77**
AQL Required	:	**1.5**
Reference Standard	:	The above consignment of goods have been inspected against Top Glove standard where samples selected at random using Single Sampling Plans for Normal Inspection of ISO 2859-1.

Declared - Size
- Quantity :

Size	Quantity (pcs)
S	100,000
M	100,000
L	100,000
Total	300,000

1. **Freedom from Holes and Visual Defects**

Size	Holes			Visual Defect (Inspection Level : G1)						Result
	Inspection level : G1, AQL 1.5			Major Defects, AQL 2.5			Minor Defects, AQL 4.0			
	Sample size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample size (pcs)	Acceptance (pcs)	Defects (pcs)	Sample size (pcs)	Acceptance (pcs)	Defects (pcs)	
S	200	7	3	200	10	6	200	14	7	Pass
M	200	7	4	200	10	7	200	14	8	Pass
L	200	7	3	200	10	6	200	14	9	Pass

2. **Dimensions**

Inspection Level : S2, AQL 4.0
Acceptance : 1

Result : Pass

Sample No.	Size	Length (mm)	Width (mm)	Thickness (single wall) (mm)	
				Fingertip	Palm
1	S	300	84	0.17	0.16
2		299	85	0.17	0.15
3		301	85	0.14	0.13
4		302	86	0.15	0.14
5	M	298	97	0.16	0.14
6		299	96	0.14	0.15
7		300	95	0.17	0.16
8		301	96	0.15	0.13
9	L	297	106	0.16	0.14
10		303	105	0.16	0.14
11		301	106	0.16	0.15
12		299	104	0.14	0.15
13		302	105	0.15	0.14

ASTM D6319 – 10 (2015) Requirement:

Size	Length (mm)	Width (mm)	Thickness (mm)
XS	≥ 220	70 ± 10	Finger & Palm (Single wall) Min 0.05
S		80 ± 10	
M	≥ 230	95 ± 10	
L		110 ± 10	
XL		120 ± 10	

3. **Physical Properties**

Inspection Level : S2, AQL 4.0
Acceptance : 1

Result : Pass

Sample No.	Size	Before Aging		After Accelerated Aging	
		Tensile Strength (MPa)	Elongation %	Tensile Strength (MPa)	Elongation %
1	S	19.2	573	15.4	482
2		15.4	587	16.1	458
3		17.5	532	15.6	532
4		17.1	602	16.0	472
5	M	16.7	554	16.5	498
6		17.3	601	17.1	505
7		18.4	546	18.1	476
8		18.3	587	16.2	481
9	L	18.3	612	16.3	484
10		16.7	598	15.8	538
11		17.4	578	16.2	486
12		18.9	563	17.1	514
13		15.9	591	16.3	474

ASTM D6319 – 10 (2015) Requirement:

Before Aging		After Accelerated Aging	
Tensile	Elongation	Tensile	Elongation
Min 14 MPa	Min 500%	Min 14 MPa	Min 400%

Note:
A test result is the median of three individual test measurement values.

4. **Powder Residue**

Sampling size, N = 5
Requirement: Max 2 mg / glove

Size	mg / glove	Result
S	0.8	Pass
M	1.2	Pass
L	0.6	Pass

CONCLUSION : We hereby certify that the above consignment of goods were determined to meet the acceptable limit of the specifications as referring to the above findings of randomly selected samples.

Prepared By : Dayana Azman
QA Chemist II

Verified By : Noor Akilah Saidin
QA Deputy General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 12, 2019

Top Glove SDN BHD
Noor Akilah Bt Saidin
Deputy General Manager, QA
Lot 4968, Jalan Teratai, Batu 6, Off Jalan Meru
Klang, 41050 MY

Re: K191279
Trade/Device Name: Sterile Latex Surgical Powder Free Gloves; Sterile Nitrile Surgical Powder Free Gloves Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Surgeon's Gloves
Regulatory Class: Class I
Product Code: KGO, LZA, LZC
Dated: September 13, 2019
Received: September 13, 2019

Dear Noor Akilah Bt Saidin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2021
See PRA Statement below.

510(k) Number *(if known)*

K191279

Device Name

Sterile Nitrile Surgical Powder Free Gloves Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*

Sterile Nitrile Surgical Powder Free Gloves Tested for Use with Chemotherapy Drugs is to be worn on the hands of healthcare professionals during surgery to prevent cross contamination between healthcare personnel and the patient.

These gloves are tested for use with Chemotherapy Drugs as per ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drug	Concentration	Breakthrough Detection Time in Minutes
Carmustin (BCNU)	3.3mg/ml	8.0
Cisplatin	1.0mg/ml	>240
Cyclophosphamide (Cytoxan)	20.0mg/ml	>240
Dacarbazine (DTIC)	10.0mg/ml	>240
Doxorubicin Hydrochloride	2.0mg/ml	>240
Etoposide (Toposar)	20.0mg/ml	>240
Fluorouracil	50.0mg/ml	>240
Paclitaxel (Taxol)	6.0mg/ml	>240
Thiotepa	10.0mg/ml	16.2

* Please note that the following drugs have extremely low permeation times:
Carmustin (BCNU) : 8.0 minutes and Thiotepa : 16.2 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2021
See PRA Statement below.

510(k) Number *(if known)*

K191279

Device Name

Sterile Latex Surgical Powder Free Gloves

Indications for Use *(Describe)*

Sterile Latex Surgical Powder Free Gloves is to be worn on the hands of healthcare professionals during surgery to prevent cross contamination between healthcare personnel and the patient.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

U.S. FOOD & DRUG
ADMINISTRATION

April 26, 2018

Top Glove SDN. BHD.
Noor Saidin
QA Deputy General Manager
Lot 4968, Jalan Teratai,
Batu 6, Off Jalan Meru
41050 Klang, Selangor
Malaysia

Re: K172923
Trade/Device Name: Nitrile Examination Powder Free Glove, White, Black, Orange
Nitrile Examination Powder Free Gloves Tested For Use With Chemotherapy Drugs, Blue
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: March 27, 2018
Received: April 9, 2018

Dear Noor Saidin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172923

Device Name
Nitrile Examination Powder Free Glove, White

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172923

Device Name
Nitrile Examination Powder Free Glove, Orange

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172923

Device Name
Nitrile Examination Powder Free Glove Tested for Use with Chemotherapy Drugs, Blue

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

These gloves were tested for use with Chemotherapy Drugs as per ASTM D6978-05 standard practice for assessment of medical gloves to permeation by chemotherapy drugs:

Chemotherapy Drug Permeation
The following chemicals have been tested with these gloves.

Chemotherapy Drugs	Concentration	Breakthrough Detection Time in Minutes
Carmustine (BCNU)	3.3 mg/ml	15.9
Ciplastin	1.0 mg/ml	> 240
Cyclophosphamide (Cytoxan)	20.0 mg/ml	> 240
Dacarbazine (DTIC)	10.0 mg/ml	> 240
Doxorubicin Hydrochloride	2.0 mg/ml	> 240
Etoposide (Toposar)	20.0 mg/ml	> 240
Fluorouracil	50.0 mg/ml	> 240
Paclitaxel (Taxol)	6.0 mg/ml	> 240
Thiotepa	10.0 mg/ml	47.3

Please note that the following drugs have low permeation time :
Carmustine (BCNU): 15.9 minutes and Thiotepa: 47.3 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 055729 0008 Rev. 01

Manufacturer:

Top Glove Sdn. Bhd.
Lot 4969, Jalan Teratai Batu 6
Off Jalan Meru
41050 Klang, Selangor D. E.
MALAYSIA

Product Category(ies):

Latex and Nitrile Surgical Powder free Glove, Sterile

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: MYQMH0319070Rev2-721423225

Valid from: 2020-02-19
Valid until: 2024-05-26

Date, 2020-02-19

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 055729 0008 Rev. 01

Facility(ies):

Top Glove Sdn. Bhd.
Lot 4969, Jalan Teratai Batu 6, Off Jalan Meru, 41050 Klang,
Selangor D. E., MALAYSIA

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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 & 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 50
1998 to 2007
Celebrating Malaysia's Enterprising Spirit

BUSINESS DIRECTION	: To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES	: 27 Factories (Malaysia, Thailand & China), 485 Production Lines, 44 Billion Gloves Per Annum, 11,000 Employees
MARKET	: Exports to more than 195 countries worldwide with Marketing offices in the USA and Germany.

EC DECLARATION OF CONFORMITY

Manufacturer's Name	: TOP GLOVE SDN. BHD
Manufacturer's Address	: Lot 4969, Jalan Teratai, 6th Mile, 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	: Powdered and Powder Free
Classification	: Class I, Non Sterile
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	: 1st December 2016

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

RA/DOC/A

November 22, 2019

· TEST REPORT ·

PN 127526

CHEMICAL ANALYTICAL SERVICES

Prepared For:

Noor Hazwa Hashim
Top Glove Sdn. Bhd.
Lot 4969, Jalan Teratai,
Batu 6, Off Jalan Meru
41050 Klang, Selangor D.E.
Malaysia

Prepared By: _____
Tiffany L Heller
Assistant Manager
Pharmaceutical Services

Approved By: _____
Ana C. Barbur, M.S.
Manager
Chemical, Microbiological, & Pharmaceutical Services

ACCREDITED
A Testing Lab
*Certificate Numbers 255.01 & 255.02

An A2LA Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2008 Registered

ISO 9001:2008
Registered

November 22, 2019

Noor Hazma Hashim
Top Glove Sdn. Bhd.

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: One bag of blue gloves identified as Nitrile Examination Powder Free Glove, CW77.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma Aldrich; Lot# 015M4004V; Expiration 04/2016
Thiotepa	Sigma Aldrich; Lot# SLBM7142V; Expiration 02/2016

COLLECTION MEDIA:

The collection media which were selected are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU)	229
Thiotepa	199

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens on: Nitrile Examination Powder Free Glove, CW77.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	#1	#2	#3		
Carmustine (BCNU)	0.098	0.099	0.096	0.098	100.4
Thiotepa	0.099	0.103	0.093	0.098	

RESULTS:

Table 5. Permeation Test Results on: Nitrile Examination Powder Free Glove, CW77.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu g/cm^2$/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	50.3 (50.3,52.8,53.2)	0.6 (0.6,0.6,0.7)	Moderate swelling and slight degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	150.6 (150.6,160.4,160.5)	0.2 (0.2,0.2,0.2)	Slight swelling and no degradation

Tiffany L. Heller
Assistant Manager
Pharmaceutical Services

Ana C. Barbur, M.S,
Manager
Chemical, Microbiological and Pharmaceutical Services

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

TOP GLOVE SDN. BHD.

PRODUCT SPECIFICATION
Nitrile Powder Free Examination Gloves (Palm Textured)

SECTION I: PRODUCT DESCRIPTION

1. 1	Type	Nitrile Examination Glove, Powder Free, Online Single Chlorinated, Non-sterile
1. 2	Matcrial	100% Synthetic Nitrile Latex
1. 3	Color	Blue
1. 4	Design and Feature	Ambidextrous, palm textured, beaded cuff
1. 5	Powder	No powder lubricant added
1. 6	Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight.
1. 7	Shelf-Life	The gloves shall have shelf life of 5 years from the date of manufacture with the above storage condition.
1. 8	Packing Style	100 pcs gloves x 10 dispensers x 1 carton
1. 9	Size Marking	The size of gloves shall be marked in the check box on every carton with black ink.

SECTION II: PERFORMANCE REQUIREMENTS

(Sampling Plan – ISO 2859 Single Normal)

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D6319-10 (2015)
2.2	Physical Properties	S2	4.0	ASTM D6319-10 (2015)
2.3	Frcedom from Holcs (Air Pump Test)	GI	1.5	In-house practice
2.4 (i) (ii)	Visual Defects: Major Visual Minor Visual	GI	 2.5 4.0	In-house practice
2.5 (i) (ii) (iii)	Packaging Defects: Regulatory Visual Critical (incl. Gloves Counting)	 GI GI S2	 ** 4.0 4.0	In-house practice
2.6	Powder Free Residue	N=5	-	ASTM D6319-10 (2015) ASTM D6124-06 (2011)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

TOP GLOVE SDN. BHD.

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length (mm)	All Sizes	300 +/- 10
Palm Width (mm)	XS S M L XL XXL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3 123 +/- 3
Thickness (mm) *single wall	All Sizes	Finger : 0.15 +/- 0.02 (Typical value: 0.14 – 0.17) Palm : 0.14 +/- 0.02 (Typical value: 0.13 – 0.16)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break (%)	Min 500 (Typical value: 500 - 600)	Min 400 (Typical value: 400 - 550)
Tensile Strength (MPa)	Min 14 (Typical value: 14 - 20)	Min 14 (Typical value: 14 - 20)

3.3 Freedom from Holes
The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Defects
The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.5 Packaging Defects
The Sample size and allowable number of non-conforming in the samples for regulatory, visual and critical packaging defects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements (Gloves Counting=100 pcs by weight per Dispenser).

3.6 Powder Free Residue
Maximum 2 mg per glove

Prepared by:
Quality Product Management System Division

Date: 17th May 2017

Checked by:
Eva Vinoni Bt Mustafa
Senior Manager, QA

Approved by:
Noor Akilah Saidin
Deputy General Manager, QA