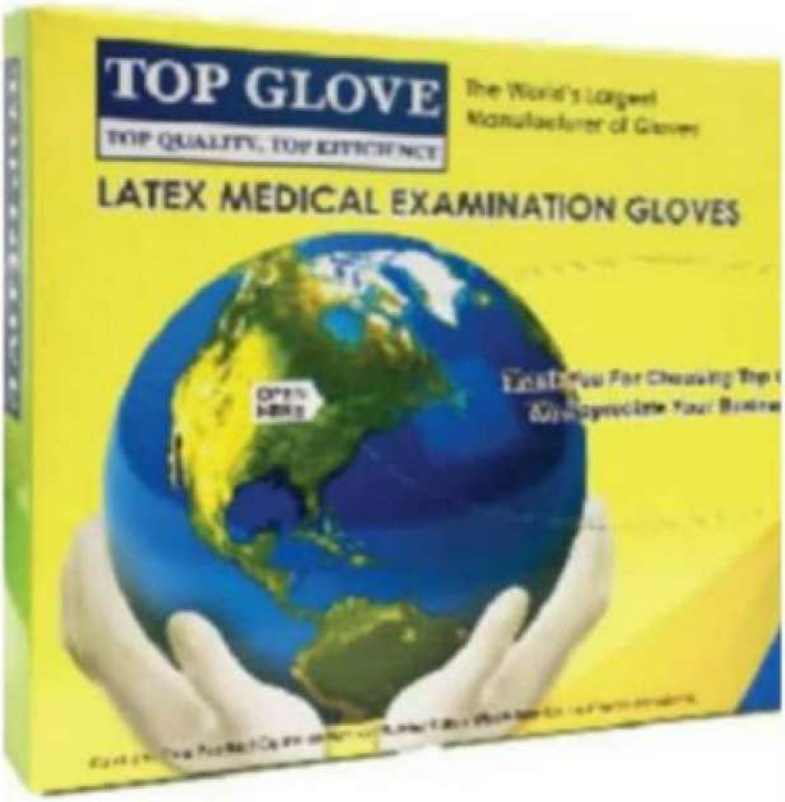
GDIH First Response & Security Group

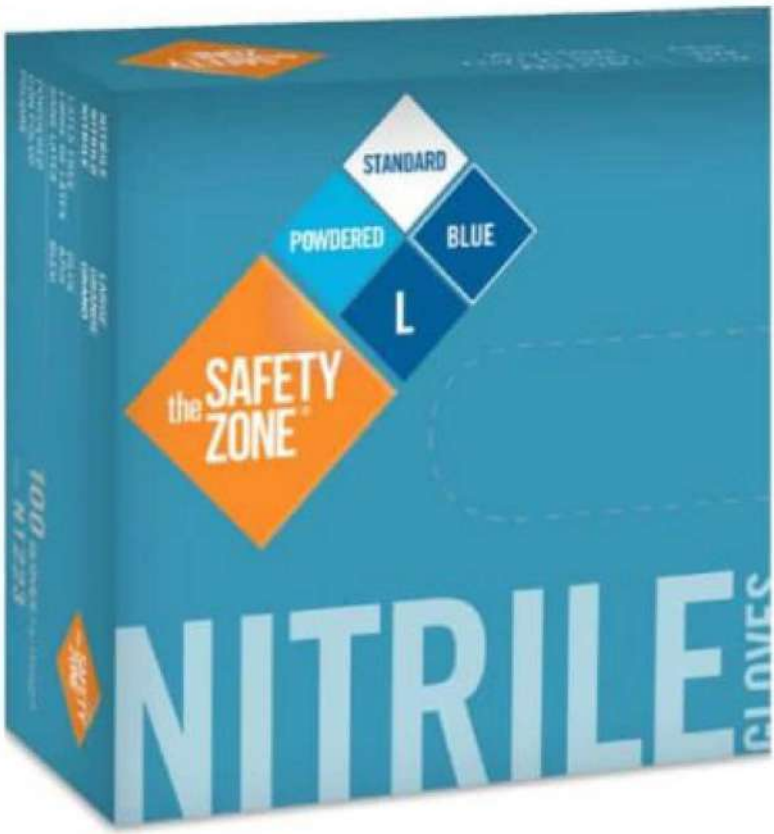
AIM-X

SRAM & MRAM GROUP

OP GLOVE

QUALITY, TOP EFFICIENCY





NITRILE GLOVE

POWDERED & POWDER-FREE

Quality Standards

- Conforms to ASTM D6319 and EN455 Standards
- Manufactured under QSR (GMP), ISO9001 : 2015 and ISO13485 : 2016 Quality Management System
- Biocompatibility tested
- Manufactured from 100% nitrile latex (Acrylonitrile-butadiene)
- Resists permeation by a wide range of chemicals as compared to natural rubber latex of the same thickness
- Conforms to MDD 93/42/EEC Class I

Glove Sizes

- Extra- small, Small, Medium, Large, Extra- large
- Marked in the check box the shipping carton with black ink

Product Specifications

Type	:	Powdered & Powder - free; non sterile
Material	:	Synthetic Nitrile Latex
Design & Features	:	Ambidextrous; textures; beaded cuff; natural white or coloured (blue/green/pink/light purple/black/red)
Storage	:	The gloves shall maintain their properties when stored in a cool and dry condition
Shelf-life	:	5 years from date of manufacturing

Physical Dimensions

DIMENSIONS	STANDARDS		
	Top Glove	ASTM D6319	EN 455
Length (mm)	240 min	220 min (size XS, S) 230min (size M, L, XL)	240 min
• Extra - small	76 ± 3	70 ± 10	≤80
• Small	84 ± 3	80 ± 10	80 ± 10
• Medium	94 ± 3	95 ± 10	95 ± 10
• Large	105 ± 3	110 ± 10	110 ± 10
• Extra - large	113 ± 3	120 ± 10	≥110
Thickness Single Wall (mm)			
• Fingers	0.05 min	0.05 min	N/A
• Palm	0.05 min	0.05 min	

Physical Properties

Property	ASTM D 6319	EN 455
Elongation at break (%)		
• Before Aging	Min 500	N/A
• After Aging	Min 400	

International Quality Certificate Awarded :

CE 0321

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	: Nitrile examination glove [powdered and powder-free]
Chemical Family	: Synthetic nitrile
Company Name	: Top Glove Sdn. Bhd.
Address	: Lot 4969, Jln Teratai, 6th Miles, Off Jln Meru, 41050 Klang, Selangor D.E. Malaysia.
Tel	: +603-3392 1992/1905
Fax	: +603-3392 1291/8410

SECTION 2: HAZARDS IDENTIFICATION

Emergency Overview
Nitrile examination gloves are not hazardous.

Hazard	: Non-hazardous.
Physical State	: Solid, film.
Colour	: Clear, coloured.

Potential Health Effects

Routes of Exposure	: Skin contact
Signs and Symptoms	: No adverse health effects are anticipated from the reasonable use of nitrile examination gloves.
Eyes	: Non-hazardous.
Inhalation	: Non-hazardous.
Skin	: Not a Primary Skin Irritant. Not a Dermal Sensitizer.
Ingestion	: This product has not been tested.

SECTION 3: COMPOSITION/ INFORMATION OF INGREDIENTS

Powdered	: Nitrile latex, ZDBC, ZDEC, zinc oxide, sulphur, titanium dioxide, potassium hydroxide, aquawax and color pigment.

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

Powder-Free : Nitrile latex, potassium hydroxide, aquawax, ZDBC, ZDEC, zinc oxide, polymeric hindered phenol, sulphur, titanium dioxide and color pigment.

SECTION 4: FIRST AID MEASURES

Steps to be taken in event of mishap:

Eyes	: Non-applicable.
Inhalation	: Non-applicable.
Skin	: Wash with soap and water.
Ingestion	: Seek medical attention if a significant quantity has been swallowed.

SECTION 5: FIRE FIGHTING MEASURES

Flammability Classification	: Non-classified. Gloves will burn but do not easily ignite.
Extinguishing Media	: Water spray, carbon dioxide, foam or dry chemical.
Firefighting Precautions	: Wear self-contained breathing apparatus and full fire-fighting turn-out gear.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Release Response : Retain for recycle or disposal.

SECTION 7 : HANDLING AND STORAGE

Nitrile examination gloves shall maintain their properties when stored in dry condition at temperature between 10°C to 30°C. Protect gloves against ultraviolet light sources such as sunlight and oxidizing agents.

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

SECTION 8: EXPOSE CONTROLS AND PERSONAL PROTECTION

Engineering Control

Use local exhaust in confined spaces where nitrile examination gloves are heated.

Personal Protective Equipment

Eyes : Not required. Use goggles if nitrile examination gloves are heated.

Inhalation : Not required.

Skin : Not required. Use heat resistant gloves if nitrile examination gloves are heated to melting state.

SECTION 9: PHYSICAL/ CHEMICAL PROPERTIES

Appearance : Ambidextrous, textured and clear or colored

Physical State : Solid

Odour : Odourless

pH : 7.35

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability : Nitrile examination gloves are stable.

Conditions to Avoid : Avoid contact with excessive heat, sparks or open flame. Avoid dust accumulation.

Hazardous Products of Decomposition : Variety of toxic off-gases may be formed when nitrile examination gloves burn and may further cause respiratory irritation.

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

The gloves shall have shelf life of 5 years from the date of manufacturer with the above storage condition.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects	: Non-toxic.
Sub-chronic and Chronic Effects	: Non-toxic.

SECTION 12: ECOLOGICAL INFORMATION

Product of Biodegradation	: Non-biodegradable.
Ecotoxicity	: Nitrile examination gloves are considered as inert.

SECTION 13: DISPOSAL CONSIDERATION

This document covers the recommended method for disposal for nitrile examination gloves manufactured by Top Glove Sdn. Bhd.

Incineration: Put appropriate amount of the gloves into the incinerator or furnace to destroy them following the requirements shown below.
Requirements:
1) Burning temperature exceeds 850°C
2) Combustion retention time is not less than 2 seconds

Note: Gloves should not be destroyed by open burning at low temperature or dispose at normal disposal area.

Other Disposal Considerations: Check with state and local authorities before discarding. The information offered here is for product as shipped. Use and/or alterations to the product such as mixing with other

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE EXAMINATION GLOVE

materials may significantly change the characteristics of the material and alter the proper disposal method.

SECTION 14: TRANSPORT INFORMATION

Non-dangerous goods.

SECTION 15: REGULATORY INFORMATION

Non-applicable.

SECTION 16: OTHER INFORMATION

This Product Safety Data Sheet is offered solely for your information. Top Glove Sdn. Bhd. provides no warranties, either express or implied, concerning the sage use of this product in your process or in combination with other substances and assumes no responsibility for the accuracy or completeness of the data contained herein. User has the sole responsibility to determine the suitability of the product for any use and the manner of use contemplated.

.....END.....

Prepared By:
QA/ RA Division

Verified By:
Pn Noor Akilah Saidin
QA/ Deputy General Manager

LEMBAGA GETAH MALAYSIA
MALAYSIAN RUBBER BOARD
RUBBER RESEARCH INSTITUTE OF MALAYSIA
Global Testing and Consultancy for Rubber (G-TACR)
Malaysian Rubber Board, 47000 Sungai Buloh, Selangor.
Tel: (6)03-61459471 Fax: (6)03-61412907
Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr

TEST REPORT DATE : 21/03/2016

REPORT NUMBER	:	QA/2016/0175/1
SUBJECT	:	Physical Properties for Examination Gloves
SUBMITTED BY	:	TOP GLOVE SDN. BHD. Lot 4969,Jalan Teratai, Batu 6,Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan. Malaysia.
ON	:	March 08, 2016

These results have been obtained on sample(s) submitted to us.

The types of test are in accordance with the customer's requirement.

The precision, measurement of uncertainty and conditions of the tests are available from the Physical Testing Laboratory, if required.

This report, except in full, shall not be reproduced without the prior approval of The Director General.

LEMBAGA GETAH MALAYSIA
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Global Testing and Consultancy for Rubber (G-TACR)
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G-TACR A Service by MRB
GLOBAL TESTING AND CONSULTANCY FOR RUBBER

ilac-MRA

STANDARDS

MS ISO/IEC 17025
TESTING/CALIBRATION
SAMM NO.008

TEST REPORT

REPORT NO : QA/2016/0175/1 DATE : 21/03/2016

Sample Description : Physical Properties for Examination Gloves

Marked : Latex Examination Polymer powder Free Gloves
Size : M

Test to Standard : Please refer to page 6 of 6.

Date of Testing : 09/03/2016 to 18/03/2016

Dimensions (mm)

Sample Reference	Length	Width	Thickness Finger	Thickness Palm
QA/2016/0175/ 1.01	241	95	0.14	0.13
1.02	243	95	0.14	0.13
1.03	242	95	0.14	0.12
1.04	243	95	0.12	0.12
1.05	241	97	0.14	0.13
1.06	240	96	0.14	0.13
1.07	234	95	0.11	0.12
1.08	240	95	0.15	0.13
1.09	244	95	0.12	0.12
1.10	240	95	0.16	0.13
1.11	240	95	0.10	0.12
1.12	242	96	0.13	0.12
1.13	234	95	0.13	0.12
Requirements	230 min	95 ± 10	0.08 min	0.08 min

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Tel: (6)03-61459471 Fax: (6)03-61412907
Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr

TEST REPORT

REPORT NO : QA/2016/0175/1 DATE : 21/03/2016

Tensile Properties Unaged

Sample Reference		Tensile Strength (MPa)	Elongation at Break (%)	Modulus at 500% (MPa)
QA/2016/0175/	1.01	20.9	670	5.0
	1.02	22.0	660	5.0
	1.03	20.5	660	5.2
	1.04	20.5	670	5.4
	1.05	20.4	690	5.2
	1.06	21.0	680	5.2
	1.07	21.0	670	5.2
	1.08	21.1	680	5.0
	1.09	19.6	650	5.4
	1.10	21.6	650	5.8
	1.11	19.6	640	5.4
	1.12	22.3	650	5.2
	1.13	19.7	670	5.0
Requirements		18.0 (min)	650 (min)	5.5 (max)

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TEST REPORT

REPORT NO : QA/2016/0175/1 DATE : 21/03/2016

Tensile Properties Aged 7d/70°C

Sample Reference		Tensile Strength (MPa)	Elongation at Break (%)	Modulus at 500% (MPa)
QA/2016/0175/	1.01	16.3	690	5.1
	1.02	17.3	710	4.8
	1.03	17.2	710	4.5
	1.04	17.2	750	3.5
	1.05	14.4	700	4.0
	1.06	17.5	730	3.4
	1.07	15.8	720	4.5
	1.08	16.9	720	3.9
	1.09	13.9	700	3.9
	1.10	16.6	700	4.0
	1.11	16.4	710	4.0
	1.12	15.1	690	4.3
	1.13	14.0	700	3.7
Requirements		14.0 (min)	500 (min)	Nil

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TEST REPORT

REPORT NO : QA/2016/0175/1 DATE : 21/03/2016

Watertightness Test

Sample Reference	No. of samples tested	No. of samples with sign of leakage
QA/2016/0175/ 1	200 pieces	Nil

(Shamheza Suhaita)
Research Officer
Physical Testing Laboratory
Malaysian Rubber Board

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TEST REPORT

REPORT NO : QA/2016/0175/1 DATE : 21/03/2016

STANDARD SPECIFICATION FOR LATEX EXAMINATION GLOVES
ASTM D3578 – 05 (Reapproved 2010)

Test	Method
Dimension (mm)	Clause 8.4
Tensile Properties Unaged	Clause 8.5.1
Tensile Properties Aged 7d/70°C	Clause 8.5.2
Watertightness	Clause 8.3

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

No. QS2 084240 0004 Rev. 01

Certificate Holder:

Certification Mark:

Scope of Certificate: Manufacturing and Distribution of Natural Latex and Synthetic Medical Examination Gloves (Powdered and Powder Free), Unsterile Gloves

Standard: ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: MYQMH0619044-721423046

Effective Date: 2020-02-03

Expiry Date: 2022-12-01

Page 1 of 1
Date of Issue: 2020-02-04

(Tina Israel)
Manager, US Certification Body
Medical and Health Services

April 15, 2016

• 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

April 15, 2016

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

Noor Hazma Hashim
Top Glove Sdn. Bhd.

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) (µg/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.

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, 2017

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: K171279
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, 2017
Received: September 13, 2017

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, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171279

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, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171279

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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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."

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Holds Certificate No: **MD 701605**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Manufacture of non-sterile natural latex, nitrile examination and surgical gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-03-22
Latest Revision Date: 2019-03-22

Effective Date: 2019-03-22
Expiry Date: 2022-03-21

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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 Result : Pass
Acceptance : 1

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 Result : Pass
Acceptance : 1

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.

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QA Deputy General Manager


TOP GLOVE
TOP QUALITY, TOP EFFICIENCY
NITRILE MEDICAL EXAMINATION GLOVES
Powder Free
FINGER TEXTURED
PALM TEXTURED
SIZE
M
MEDIUM
100
Gloves
(by weight)