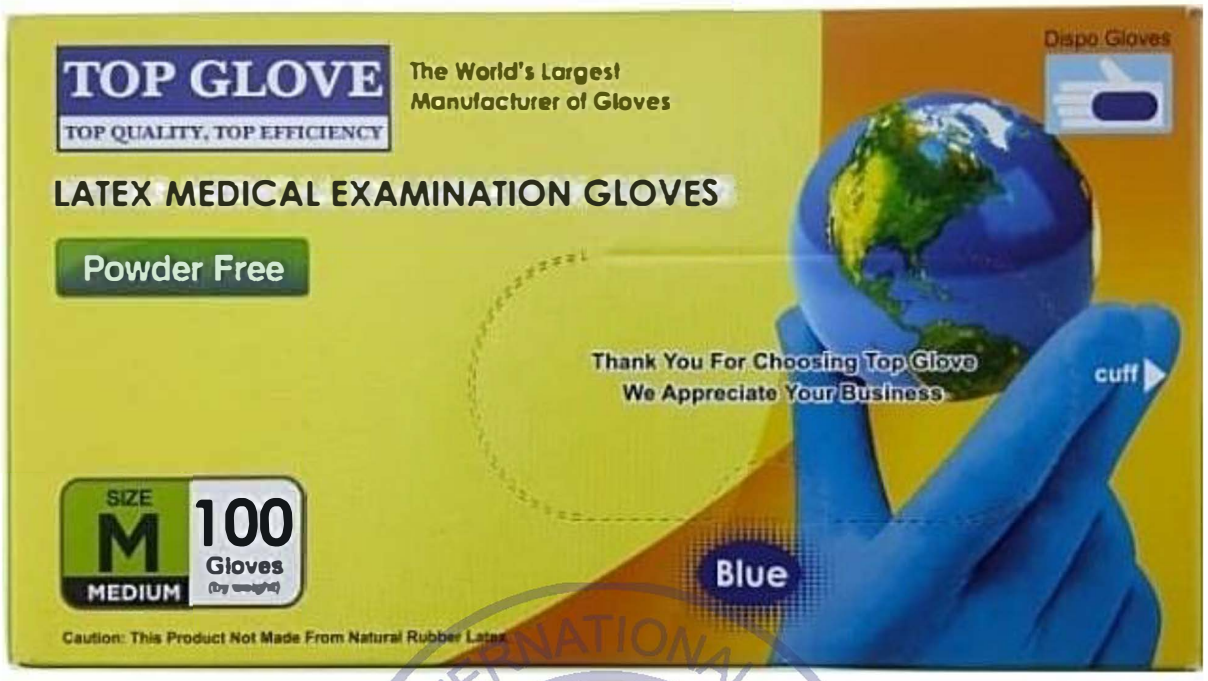
HQ: Suites 28-3 Binjai 8 Premium SOHO
Kuala Lumpur City Centre (KLCC) Lorong Binjai
50400 Kuala Lumpur

Lab: TT BIOTECH Lab, No.8 SME Technology Park
Jalan PJU 3/39, Sunway Damansara
47810 Petaling Jaya, Selangor

+603 21815887 admin@mytracetag.com www.mytracetag.com



TOP GLOVE

TOP QUALITY, TOP EFFICIENCY

THE WORLD'S LARGEST MANUFACTURER OF GLOVES

LATEX 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

LATEX 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 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

8enennt durch/Designated by
Zentraisteiie der Lander
ffir Gesundheltsschurz
bel ArzneimTMeln und
Nedizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production ouality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class lla, llb 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 Powderfree Glove, Sterile

The Certification Body of TUV SUD 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 lib and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

TRACE TAG INTERNATIONAL (M) SDN BHD
971819-A

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

TUV SUD Product Service GmbH is Notified Body with identification no. 0123
TUV SUD Product Service GmbH • Certification Body • Ridlerstra£e 65 • 80339 Munich • Germany

Zentra Istelle der Land er
fur Gesundheirs schutz
be i Arz ne i mittein und t
Medizinprodukten
ww
ZLG- BS-244.10.OB

Prod u ct Service

EC Certificate

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

TRACE TAG INTERNATIONAL (ASIA) SDN BHD
971819-A

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

TUV SUD Product Service GmbH is Notified Body with identification no. 0123

TUV SUD Product Service GmbH • Certification Body • Ridlerstra0e 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM T1327-07-00

Product Service

Certificate

No. Q6 055729 0010 Rev. 02

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

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

Certification Mark:

SGD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: Manufacture and Supply of
1. Non-Sterile Natural Rubber Latex Examination Glove
2. Non-Sterile Synthetic Rubber Latex Examination Glove
3. Sterile Natural Rubber Latex Surgical Glove
4. Sterile Synthetic Rubber Latex Surgical Glove

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TUV SUD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: MYQMH1218060-721421725

Valid from: 2019-01-28
Valid until: 2020-04-30

Date, 2019-01-28

Stefan Prei£

TUV SUD Product Service GmbH • Certification Body • Ridlerstra£e 65 • 80339 Munich • Germany

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

PRODUCT SPECIFICATION
Latex Powder Free Examination Glove (Palm Textured)

SECTION I: PRODUCT DESCRIPTION

1. 1	Type	Latex Examination Glove, Powder Free, Online Single Chlorinated, Non-sterile
1. 2	Material	Natural High-Grade Latex Butadiene Rubber
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	1.5	ASTM D6319-19 (2015)
2.2	Physical Properties	S2	1.5	ASTM D6319-19 (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 D3578-05 (2015) ASTM D6124-06 (2011)
2.7	Mix Size / Mix Glove / Mix Hand	Not Allowed		

**Unacceptable at any level

SECTION III: PERFORMANCE SPECIFICATION

3.1 Dimensions

Description	Size	Standard
Length (mm)	All Sizes	Min 240
Palm Width (mm)	XS S M L XL	76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3
Thickness (mm) *single wall	All Sizes	Finger: 0.05 +/- 0.05 (Typical value: 0.11 – 0.14) Palm: 0.05 +/- 0.05 (Typical value: 0.10 – 0.12)

3.2 Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break (%)	Min 650 (Typical value: 650 – 750)	Min 500 (Typical value: 500 – 600)
Tensile Strength (MPa)	Min 18 (Typical value: 18 – 22)	Min 14 (Typical value: 14 – 18)

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 2859-1Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

3.4 Visual Inspection

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 sample 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 Requirement (Gloves Counting = 100 pcs by weight per Dispenser).

3.6 Powder Free Residue

Maximum 2 mg per glove

Prepared by: Date: 31st May 2016
Quality Product Management System Division

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
LATEX EXAMINATION GLOVE

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	: Latex examination glove [powdered, powder-free]
Chemical Family	: Natural rubber glove
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
Latex 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 latex 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	: Natural rubber latex, corn starch, calcium carbonate, ZDBC, ZDEC, zinc oxide, polymeric hindered phenol, sulphur and titanium dioxide.
Powder-free	: Natural rubber latex, cyclaron-1, ZDBC, ZDEC, zinc oxide, polymeric hindered phenol, sulphur, wax and titanium dioxide.

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
LATEX EXAMINATION GLOVE

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 does 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

Latex 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
LATEX EXAMINATION GLOVE

SECTION 8: EXPOSE CONTROLS AND PERSONAL PROTECTION

Engineering Control

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

Personal Protective Equipment

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

Inhalation : Not required.

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

SECTION 9: PHYSICAL/ CHEMICAL PROPERTIES

Appearance : Ambidextrous
Textured, embossed inside/ outside
Clear or coloured

Physical State : Solid

Odour : Odourless

pH : 7.35

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability : Latex examination gloves are stable.

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

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
LATEX EXAMINATION GLOVE

Hazardous Products : Variety of toxic off-gases may be formed when cast polyethylene of decomposition gloves burn and may further cause respiratory irritation. 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 : Latex examination gloves are considered as inert.

SECTION 13: DISPOSAL CONSIDERATION

This document covers the recommended method for disposal for latex 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 850ºC
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.

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
LATEX EXAMINATION GLOVE

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 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……...

TOP GLOVE SDN BHD
TEST REPORT

Type Of Glove	:	**Latex 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 a 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, 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 Latex 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: 0MB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

51 O(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	50mg/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)*

D Prescription Use (Pari 21 CFR 801 Subpart D) 12] Over-The-Counter Use (21 CFR 801 Subpar1 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 0MB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

51 O(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 o f healthcare professionals during surge1y to prevent cross contamination between healthcare personnel and the patient.

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

D 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 sponso1; and a person is not required to respond to, a collection of info1mation unless it displays a currently valid 0MB number."

April 15, 2016

. TEST REPORT .

PN 127526

CHEMICAL ANALYTICAL SERVICES

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April 15, 2016

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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 mQ/ml (3,300 oom)	10% Ethanol Aaueous Solution
Thiotepa, 10.0 mg/ml (10,000 oom)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UVNIS 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; UVNIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UVNIS Spectrometer Lambda 25

UVNIS 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 Win lab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UVNIS 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) #1	#2	#3	Average (mm)	Weight/Unit Area (g/m2)
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 Glave, 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

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AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Management Service

CERTIFICATE

The Certification Body
of TOV SOD Management Service GmbH
certifies that

Rubberex Alliance Sdn. Bhd.
Lot 138201, Off 3/4 Mile Jalan Bercham,
Kawasan Perindustrian Bercham
31400 Ipoh, Perak
Malaysia

97 a elt ii e d and appl'1es
a Quality Management System for

Production and Distribution of
Synthetic Latex Examination Gloves.

An audit was eu med, Report No. **721420226.**

Proof has been furnished that the requirements
according to

ISO 9001 :2015

are fulfilled.

The certificate is valid from **2018-08-30** until **2021-09-17.**

Certificate Registration No.: **12 100 50660 TMS.**

Product Compliance Management
Munich, 2018-09-04

DAkkS Deutsche Akkreditlcrungs.stelle D-ZM-14143-01-00