TOP GLOVE

TOP QUALITY, TOP EFFICIENCY

Dolphin®

NITRILE EXAMINATION GLOVE

Type	Powdered & Powder-Free, Non-sterile
Material	100% Synthetic Nitrile Latex
Colour	**Powdered:** Blue, White **Powder-Free:** Blue, White, Black, Orange, Green, Pink, Red, Yellow, Light Purple, Cool Blue, Cornflower Blue, Grey, Magenta (Other colours available upon request)
Design & Features	Ambidextrous, finger or palm textured surface, beaded cuff **Powdered:** USP grade absorbable cornstarch **Powder-Free:** Polymer coated, online single chlorinated or offline double chlorinated
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

FUNCTIONAL BENEFITS:

- Protection from unwanted and dangerous substances
- Beaded cuff ensures easy donning and prevent roll down
- Superior strength with better puncture resistance
- Finger or palm textured enhanced wet and dry grip
- Thinner gauge improves tactile sensitivity
- Custom design enhanced comfort and fit
- Provide an alternative solution for individuals who are allergic to Natural Rubber Latex

QUALITY STANDARDS:

- Conforms to ASTM D6319 and EN 455 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

INTERNATIONAL QUALITY SYSTEM CERTIFICATE AWARDED:

Dimension	Standard		
	Top Glove	ASTM D6319	EN 455
Length (mm)	Min 230, Min 240 or 300 +/- 10	Min 220 (XS, S) Min 230 (M, L, XL)	Min 240
Palm Width (mm) XS S M L XL	 76 +/- 3 84 +/- 3 94 +/- 3 105 +/- 3 113 +/- 3	 70 +/- 10 80 +/- 10 95 +/- 10 110 +/- 10 120 +/- 10	 ≤ 80 80 +/- 10 95 +/- 10 110 +/- 10 ≥ 110
Thickness : Single Wall (mm) Finger Palm	 Min 0.05 Min 0.05	 Min 0.05 Min 0.05	 N/A N/A

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

1.1) BIOCOMPATIBILITY TESTED

Reference: ISO 10993-10 (Test for Skin Irritation and Skin Sensitization)

Purpose: Biological evaluation for medical devices for irritation and delayed type hypersensitivity

Property	Test Results
Primary Skin Irritation	Passes Not a primary skin irritant under condition of the study
Skin Sensitization	Passes Not a contact sensitizer under condition of the study

1.2) VIRAL PENETRATION TESTED

Reference: ASTM F1671 - Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood - Borne Pathogens Using Phi-X 174 Bacteriophage Penetration as a Test System

Purpose: To test the barrier protection of the gloves from the passages of the viruses

Viral Penetration	Test Results
	Passes

Remarks: Applicable to selected products. Please liaise with our representative for further details.

1.3) HEAVY METAL TESTED

Purpose: To ensure gloves are free from heavy metals substances

Chemical Test (s)	Test Results (mg/kg)
Cadmium (Cd)	Not Detected
Lead (Pb)	Not Detected
Mercury (Hg)	Not Detected
Arsenic (As)	Not Detected
Antimony (Sb)	Not Detected
Tin (Sin)	Not Detected

Remarks: Applicable to selected products. Please liaise with our representative for further details.

1.4) CHEMICAL RESIDUE TESTED

Purpose: To ensure gloves are free from any chemical substances

Chemical Test (s)	Test Results (µg/g)
Butylated Hydroxyanisole (BHA)	Not Detected
Butylated Hydroxytoluene (BHT)	Not Detected
Diphenyl Thiourea (DPT)	Not Detected
Mercaptobenzothiazole (MBT)	Not Detected
Tetramethylthiuram Disulphide (TMTD)	Not Detected
Zinc Dibutyldithiocarbamate (ZDBC)	Not Detected
Zinc Diethyldithiocarbamate (ZDEC)	Not Detected
Zinc Dimethyldithiocarbamate (ZDMC)	Not Detected
Zinc Mercaptobenzimidazole (ZMBI)	Not Detected
Zinc Mercaptobenzothiazole (ZMBT)	Not Detected
Zinc Pentamethyleneditithiocarbamate (ZPMC)	Not Detected

Remarks: Applicable to selected products. Please liaise with our representative for further details.

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PRODUCT & ISO CERTIFICATION

In line with our business direction of providing consistently high quality gloves at efficient low cost, we emphasise on stringent quality control procedures factories. We strictly follow the quality standards in accordance to the awards accredited to us:-

SINCE 2019

Product Halal certificate for CPE/TPE variant
by Jabatan Agama Islam Selangor (JAIS) and Jabatan Kemajuan Islam Malaysia (JAKIM)

Top Glove Technology (Thailand) Co., Ltd.
Address: 188 Moo 5, Tambol Pangla, Amphur Sadao, Songkhla 90170, Thailand
is FSC™ Chain of Custody Certified (license code FSC™ C149477)
by SGS South Africa (Pty) Ltd.

SINCE 2011

ISO 14001:2015
by IQNet International Certification Network

SINCE 2010

Certificate of Conformity
by Malaysia Rubber Board

SINCE 2005

ISO 9001:2015/HACCP
by NQA Global Assurance Certificate

ISO 9001:2008
by TUV Management Service GmbH

ISO 13485:2003
by TUV Management Service GmbH

SINCE 2004

Medical Device License
by Health Canada

Food Conformance Certificate
by SGS,UK

ISO 13485:2003(CMDCAS)
by SGS United Kingdom Ltd.System & Services Certification

SINCE 2002

CE Registration
by Competent Authority,Bezirksregierung

CGSB Listing Program
by Government of Canada

EC-Type Examination Certificate
by SATRA,UK

SINCE 1999

ISO 13485:2003
by SGS United Kingdom Ltd.System & Services Certification

Directive 93/42/EEC-Surgical Gloves
by SGS United Kingdom Ltd.System & Services Certification

SMG(Standard Malaysia Glove)Certificate
by SMG Panel Malaysia Rubber Board

SINCE 1991

FDA 510(K)Pre-market Application
by Food and Drug Administration,USA

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE DISPOSABLE GLOVE

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE DISPOSABLE 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 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 disposable 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.

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SAFETY DATA SHEET
NITRILE DISPOSABLE GLOVE

SECTION 8: EXPOSE CONTROLS AND PERSONAL PROTECTION

Engineering Control

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

Personal Protective Equipment

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

Inhalation : Not required.

Skin : Not required. Use heat resistant gloves if nitrile disposable 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 : Nitrile disposable gloves are stable.

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

Hazardous Products : Variety of toxic off-gases may be formed when nitrile disposable

TOP GLOVE SDN. BHD.

SAFETY DATA SHEET
NITRILE DISPOSABLE GLOVE

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 : Nitrile disposable 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^{o}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.

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SAFETY DATA SHEET
NITRILE DISPOSABLE 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……...

Prepared By:
QA/ RA Division

Verified By:
Mrs. Noor Akilah Saidin
QA/ Deputy General Manager

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

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

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 : 3rd October 2014

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

RA/DOC/A

FDA

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Establishment Registration & Device Listing

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Proprietary Name:	Patient Examination Gloves
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA[6]
Device Class:	1
Regulation Number:	880.6250[7]
Medical Specialty:	General Hospital
Registered Establishment Name:	TOP GLOVE SDN. BHD.[8]
Registered Establishment Number:	8043848
Premarket Submission Number:	K122999[9]
Owner/Operator:	TOP GLOVE SDN. BHD.[10]
Owner/Operator Number:	9004187
Establishment Operations:	Manufacturer; Repackager/Relabeler

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7. /scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=880.6250
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Establishment Registration & Device Listing

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Establishment:
TOP GLOVE SDN. BHD.
LOT 4969,JALAN TERATAI,BATU 6
OFF JALAN MERU
KLANG Selangor, MY 41050
Registration Number: 8043848
FEI Number*: 3003564842
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
TOP GLOVE SDN. BHD.[6]
LOT 4969, JALAN TERATAI, BATU 6
OFF JALAN MERU
KLANG, Selangor MY 41050
Owner/Operator Number: 9004187[7]

Official Correspondent:
Tong Siew Bee
LOT 4969, JALAN TERATAI, BATU 6
OFF JALAN MERU
KLANG, Selangor MY 41050
Phone: 60-3339-21992

US Agent:
David Lim
165 N. Aspan Ave
Azusa , CA US 91702
Phone: 626 9697838 Ext 108
Fax: 626 9697823
Email: Limdavid33@Gmail.Com

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   start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9004187&OwnerOpe
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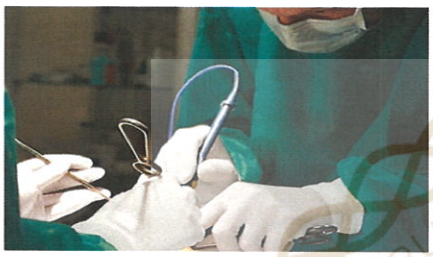
NITRILE GLOVE

MEDICAL



NITRILE SURGICAL GLOVE

Nitrile Surgical Glove is a disposable device intended for surgical purposes that are worn on the h healthcare personnel during surgery to prevent contamination between healthcare personnel anc

- European Countries : Class IIa Directive MDD 93/42/EEC
- United States of America (USA) : Class I

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NITRILE EXAMINATION GLOVE

Nitrile Examination Glove is a disposable device intended for medical purposes that are worn on t hand to prevent contamination between the patient and examiner.

- European Countries : Class I Directive MDD 93/42/EEC
- United States of America (USA) : Class I with approved 21.CFR.820 FDA 510(K)

MORE DETAILS DOWNLOAD BROCHURE SEND ENQUIRY

NITRILE EXAMINATION GRIPPLUS™ GLOVE

GripPlus™ Nitrile Glove with modified and enhanced grip, which provides superior gripping prope applying additional force. The gloves possess good tactile sense and non-slip qualities that are exc holding dry, wet and oily object. Its custom design enhances fit and comfort.

- European Countries: Class I Directive MDD 93/42/EEC

MORE DETAILS DOWNLOAD BROCHURE SEND ENQUIRY

NITRILE EXAMINATION PEARLY PINK GLOVE

The Pearly Pink Nitrile Glove in a trendy glistening pink, which exerts a calming effect on users.

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FDA U.S. FOOD & DRUG ADMINISTRATION

510(k) Premarket Notification

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Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K172923
Device Name	Nitrile Examination Powder Free Glove, White, Black, Orange, Nitrile Examination Powder Free Gloves Tested For Use With Chemotherapy Drugs, Blue
Applicant	Top Glove Sdn. Bhd. Lot 4968, Jalan Teratai, Batu 6 Off Jalan Meru Klang, MY 41050
Applicant Contact	Noor Akilah Binti Saidin
Correspondent	Top Glove Sdn. Bhd. Lot 4968, Jalan Teratai, Batu 6 Off Jalan Meru Klang, MY 41050
Correspondent Contact	Noor Akilah Binti Saidin
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Subsequent Product Code	LZC[25]
Date Received	09/25/2017
Decision Date	04/26/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement[26]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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26. http://www.accessdata.fda.gov/cdrh_docs/pdf17/K172923.pdf

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16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZA
23. /scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=880.6250
24. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZA
25. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZC
26. http://www.accessdata.fda.gov/cdrh_docs/pdf17/K172923.pdf

FDA U.S. FOOD & DRUG ADMINISTRATION

510(k) Premarket Notification

Device Classification Name	Polymer Patient Examination Glove[22]
510(K) Number	K172923
Device Name	Nitrile Examination Powder Free Glove, White, Black, Orange, Nitrile Examination Powder Free Gloves Tested For Use With Chemotherapy Drugs, Blue
Applicant	Top Glove Sdn. Bhd. Lot 4968, Jalan Teratai, Batu 6 Off Jalan Meru Klang, MY 41050
Applicant Contact	Noor Akilah Binti Saidin
Correspondent	Top Glove Sdn. Bhd. Lot 4968, Jalan Teratai, Batu 6 Off Jalan Meru Klang, MY 41050
Correspondent Contact	Noor Akilah Binti Saidin
Regulation Number	880.6250[23]
Classification Product Code	LZA[24]
Subsequent Product Code	LZC[25]
Date Received	09/25/2017
Decision Date	04/26/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement[26]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZA
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24. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZA
25. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=LZC
26. http://www.accessdata.fda.gov/cdrh_docs/pdf17/K172923.pdf

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TPLC - Total Product Life Cycle

CDRH SuperSearch[6]

New Search show TPLC since 2018 Back to Search Results

Device	Polymer Patient Examination Glove
Regulation Description	Non-powdered patient examination glove.
Definition	A nitrile (or polymer) patient examination glove is a disposable device made of nitrile rubber or synthetic polymers that may or may not bear a trace amount of residual powder, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Product Code	LZA
Regulation Number	880.6250[22]
Device Class	1

Premarket Reviews

Manufacturer	Decision	
ECO MEDI GLOVE SDN BHD		
	SUBSTANTIALLY EQUIVALENT[23]	2
EVER GLOBAL (VIETNAM) ENTERPRISE CORPORATION		
	SUBSTANTIALLY EQUIVALENT[24]	1
GX CORPORATION SDN BHD		
	SUBSTANTIALLY EQUIVALENT[25]	1
HARTALEGA NGC SDN. BHD.		
	SUBSTANTIALLY EQUIVALENT[26]	4
HARTALEGA SDN BHD		
	SUBSTANTIALLY EQUIVALENT[27]	2
IMCO LLC		
	SUBSTANTIALLY EQUIVALENT[28]	1
KIMBERLY-CLARK CORP.		
	SUBSTANTIALLY EQUIVALENT[29]	1
KIMBERLY-CLARK CORPORATION		
	SUBSTANTIALLY EQUIVALENT[30]	1
MEDLINE		
	SUBSTANTIALLY EQUIVALENT[31]	4
MEDLINE INDUSTRIES, INC.		
	SUBSTANTIALLY EQUIVALENT[32]	4
MERCATOR MEDICAL (THAILAND) LTD.		
	SUBSTANTIALLY EQUIVALENT[33]	3
RIVERSTONE RESOURCES SDN BHD		
	SUBSTANTIALLY EQUIVALENT[34]	3
SHOWA BEST GLOVE, INC.		
	SUBSTANTIALLY EQUIVALENT[35]	1
SYNTEX HEALTHCARE PRODUCTS CO., LTD		
	SUBSTANTIALLY EQUIVALENT[36]	1
TOP GLOVE SDN. BHD.		
	SUBSTANTIALLY EQUIVALENT[37]	1

1. K172923 Nitrile Examination Powder Free Glove, White, Blac[38] ...

Device Problems

Patient-Device Incompatibility[39]	1
Total Device Problems	1

Recalls

Manufacturer	Recall Class	Date Posted
1 Cardinal Health 200, LLC[40]	II	May-06-2019

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. ../cfcfr/cfrsearch.cfm?fr=880.6250
23. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=ECO%20MEDI%20GLOVE%20SDN%20BHD&pmndecision=SUBSTANTIALLY%20EQUIVALENT#EC MEDI GLOVE SDN BHD
24. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=EVER%20GLOBAL%20%28VIETNAM%29%20ENTERPRISE%20CORPORATION&pmndecision=SU GLOBAL (VIETNAM) ENTERPRISE CORPORATION
25. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=GX%20CORPORATION%20SDN%20BHD&pmndecision=SUBSTANTIALLY%20EQUIVALENT#GX CORPORATION SDN BHD
26. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=HARTALEGA%20NGC%20SDN%2E%20BHD%2E&pmndecision=SUBSTANTIALLY%20EQUIVALEN NGC SDN. BHD.
27. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=HARTALEGA%20SDN%20BHD&pmndecision=SUBSTANTIALLY%20EQUIVALENT#HARTALEGA SDN BHD
28. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=IMCO%20LLC&pmndecision=SUBSTANTIALLY%20EQUIVALENT#IMCO LLC
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30. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=KIMBERLY%2DCLARK%20CORPORATION&pmndecision=SUBSTANTIALLY%20EQUIVALENT#KIME CLARK CORPORATION
31. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=MEDLINE&pmndecision=SUBSTANTIALLY%20EQUIVALENT#MEDLINE
32. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=MEDLINE%20INDUSTRIES%2C%20INC%2E&pmndecision=SUBSTANTIALLY%20EQUIVALENT#M INDUSTRIES, INC.
33. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=MERCATOR%20MEDICAL%20%28THAILAND%29%20LTD%2E&pmndecision=SUBSTANTIALLY%2 MEDICAL (THAILAND) LTD.
34. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=RIVERSTONE%20RESOURCES%20SDN%20BHD&pmndecision=SUBSTANTIALLY%20EQUIVALEN RESOURCES SDN BHD
35. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=SHOWA%20BEST%20GLOVE%2C%20INC%2E&pmndecision=SUBSTANTIALLY%20EQUIVALENT BEST GLOVE, INC.
36. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=SYNTEX%20HEALTHCARE%20PRODUCTS%20CO%2E%2C%20LTD&pmndecision=SUBSTANTIAL HEALTHCARE PRODUCTS CO., LTD
37. ./tplc.cfm?ID=2701&min_report_year=2018&manufacturer=TOP%20GLOVE%20SDN%2E%20BHD%2E&pmndecision=SUBSTANTIALLY%20EQUIVALENT#TO GLOVE SDN. BHD.
38. ../cfPMN/pmn.cfm?start_search=1&knumber=K172923
39. ../cfmaude/results.cfm?start_search=1&searchyear=&productcode=LZA&productproblem=2682&devicename=&knumber=k&pmanumber=p&manufacturer=&brandname=
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Batu 6
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41050 KLANG
Selangor D E
Malaysia

Notified Body: 2777

SATRA customer number: P0130

EU Type-Examination Certificate

Certificate number: 2777/10648-04/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

EB201

Description:

Nitrile examination powder free gloves available in:
Black, White, Red, Pink, Blue, Light Purple, Green, Forest Green, Cool Blue, Cornflower Blue, Violet Blue, Marlin Blue, Sky Blue, Dodger Blue, Pearlescent Pink, Harmony Blue, Avocado.

Sizes:

6 (XS) – 10 (XL)

Classification:

EN ISO 374-1:2016/Type B	**Level**	**EN374-4:2013**
37% Formaldehyde	6	3.1%
40% Sodium Hydroxide	6	-25.6%
30% Hydrogen Peroxide	2	17.0%

EN ISO 374-5:2016	
Resistance to Bacteria and Fungi	Pass
Resistance to Virus	Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0265112/1749/EN/A, CHM0265112/1749/EN/B, CHM0265112/1749/SPT, CHM0272621/1826/JS, CHM0275215/1836/LH, CHM0275215/1836/LH/E, CHM0275215/1836/LH/D, CHM0275215/1836/LH/A/Final
TUV: 7191143339-CHM16-01-RC

Signed on behalf of SATRA:

Hannah Coe

Geoff Graham

Date first issued: 25/06/2018
Date of issue: 14/03/2019

Expiry date: 25/06/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.