



ベストセーフ

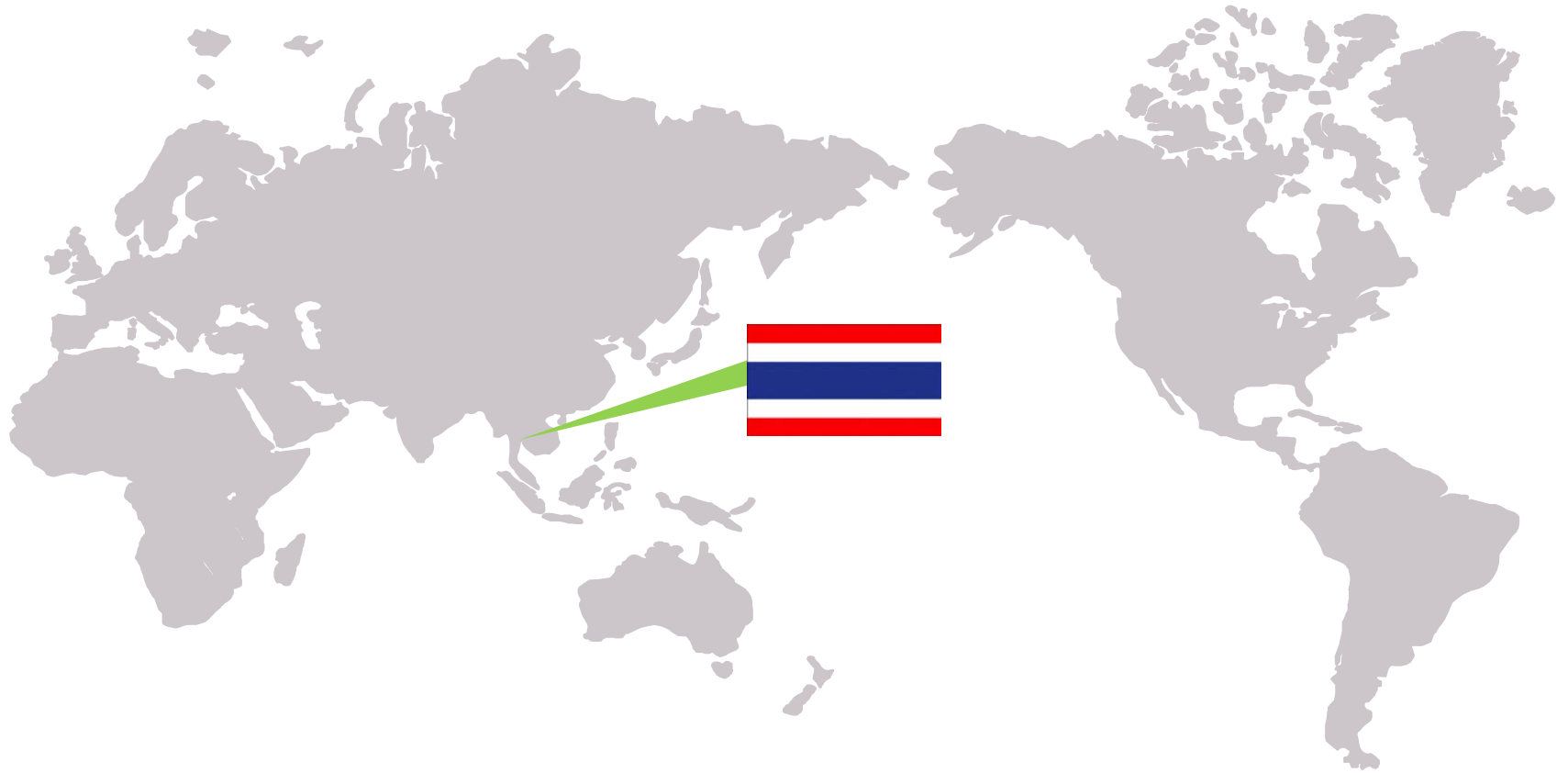
BESTSAFE

BESTSAFE GLOVE CO.,LTD

บริษัท เบสท์เซฟ โกลฟ จำกัด

BESTSAFE GLOVE CO.,LTD

Made in Thailand



NEW HEAD OFFICE



Manufacturing



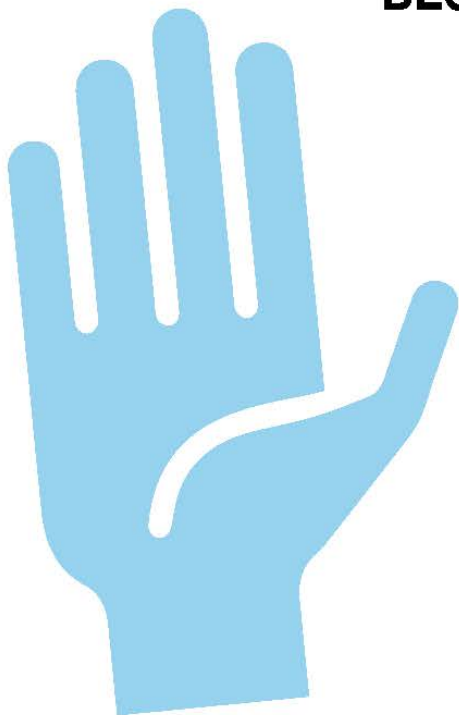
Our main products :

- Nitrile glove
- Latex glove
- PVC glove



ベストセーフ
BESTSAFE
BESTSAFE GLOVE CO.,LTD

BESTSAFE GLOVE CO.,LTD.



BESTSAFE.CO.TH



ベストセーフ
BESTSAFE
BESTSAFE GLOVE CO.,LTD



Powder and
Latex **Free**

Crafted from
durable **synthetic
polymer**

Nitrile design
is more resistant
to oils, chemicals
and acids

Superior strength
for long lasting
wear

Comfortable, easy
**on and off
design**

CE EN374
Certified





RECOMMENDATION

- KEEP IN DRY PLACE-AVOID SUNLIGHT.
- KEEP AWAY FROM INSECTS.

DIRECTION

- AVOID PUNCTURED BY SHARP OBJECTS.
- PUT ON THE CORRECT HANDS.
- WHEN DONE USING, REVERSE THE INSIDE OF GLOVES AND AVOID TOUCHING GLOVE SURFACE-DISPOSE IN TRASH CAN.

PRODUCED BY

PIYAMANE GROUP LTD.,PART
52/40 Watkodhin-Kaophai rd. T.Tubma,
A.Muang, Rayong, Rayong, 21000
TEL : (+66)38-949880
EMAIL : EXPORT@PIYAMANE.COM

LOT : 05013

DISTRIBUTED BY

BESTSAFE CO.,LTD
52/43 Watkodhin-Kaophai rd. T.Tubma,
A.Muang, Rayong, Rayong, 21000
TEL : (+66)38-949880
EMAIL : SALES@BESTSAFE.COM

MFG : 052020

ベストセーフ
BESTSAFE
WWW.BESTSAFE.CO.TH



EXP. : 052023 0117

Examintation Gloves | Nitrile Powder Free
BESTSAFE
WWW.BESTSAFE.CO.TH
BEST GLOVE-NITRILE

Spec of NITRILE GLOVE

- ❖ Protects against a wide range of chemicals as compared to natural rubber latex of the same thickness. Superior strength with better puncture resistance.
- ❖ Biologically Compatible.
- ❖ Softness and shape provides excellent comfort. Beaded cuff enhances donning and prevents rollback. High tensile strength and elongation.
- ❖ Ambidextrous and straight fingers.
- ❖ Free from dirt marks, oil stains, embedded foreign particles, coagulum etc. Completely free of talc.
- ❖ Non Allergic.
- ❖ Polymer Coated for easy donning.
- ❖ Fully textured grip for great performance in all conditions.

Spec of NITRILE GLOVE

GLOVE SIZES

S, M, L, XL


GLOVE COLOUR

❖ Blue

PRODUCT SPECIFICATIONS

- ❖ Material – Synthetic Nitrile Rubber Latex (Acrylonitrile Butadiene) Length – 240 mm +/- 5mm
- ❖ Weight – 3.5 to 5.0g +/- 0.3g per piece Cuff Style – Beaded
- ❖ Surface – Palm Textured AQL – 1 - 2.5

MSDS NITRILE

MATERIAL SAFETY DATA SHEET				
SECTION 1: PRODUCT IDENTIFICATION				
NAME BESTSAFE GLOVE CO.,LTD		ADDRESS 52/43 Watkodhin-Kaophai rd. T.Tubma, A.Muang, Rayong, Rayong. 21000		
TELEPHONE NUMBER (+66)38-949880		DATE PREPARED		
COMMON NAME (USED ON LABEL) Nitrile Powder Free Examination Gloves		CHEMICAL FAMILY Carboxylated Butadiene Acrylonitrile Polymer Latex		
APPLICATION Hospital / Dental / Laboratory / Cleaning Industrial / Hotel / Cosmetic / Food		TRADENAME & SYNONYM Best Glove-Nitrile Examination glove - Nitrile Powder Free		
SECTION 2: HAZARDOUS INGREDIENTS				
HAZARDOUS COMPONENT	CAS #	%(WT)	TLV	PEL
N/A	N/A	N/A	N/A	N/A
<small>PEL: Permissible Exposure Limit established by Occupational Safety and Health Administration (OSHA). TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987-1988.</small>				
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS				
CHEMICAL COMPOSITION All chemicals used are non-toxic/non-hazardous. Butadiene Acrylonitrile Latex Sodium Dodecylbenzenesulfonate Sulphur, Zinc Oxide, Zinc Din. butyldithiocarbamate, Titanium Dioxide, Paraffin Wax Emulsion Coating Ingredient Colloidal oatmeal and Co Constituent units, Sodium Benzoate, Processing Aid				
SECTION 4: FIRST AID MEASURE				
If reaction in the form of skin irritation is noticed, remove gloves immediately and wash affected part with saline water. If there is no relief, seek medical reactions.				
SECTION 5: FIRE FIGHTING MEASURE				
FLASHPOINT	AUTOIGNITION TEMPERATURE	FLAMMABLE LIMITS IN AIR		
N/A	N/A	N/A		
EXTINGUISHING MEDIA Chemical foam and dry chemical may be used.				
FIRE-FIGHTING PROCEDURES Use standard procedures for combustion material fires, including approved self-contained breathing apparatus.				
FIRE AND EXPLOSION HAZARDS No fire or explosion hazards are associated with these products. They will melt at elevated temperatures.				
SECTION 6: ACCIDENTAL RELEASE MEASURES				
BIOCOMPATIBILITY The chemical formulation of the gloves and surface lubrication materials does not contain any substances normally known to be harmful to the user or to any person with whom the gloves come into contact.				
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE Nitrile Powder Free Gloves are not expected to cause any adverse health effects.				
SECTION 7: HANDLING AND STORAGE				
PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE Store in a dry, cool and ventilated area. Do not store above 104 °F (40 °C). Shield open box from direct sunlight, fluorescent lighting and x-rays. Improper storage will decrease usable life.				

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION				
EYE PROTECTION Not necessary under conditions of intended use.		SKIN PROTECTION Not necessary under conditions of intended use.		
RESPIRATORY PROTECTION Not necessary under conditions of intended use.		VENTILATION Not necessary under conditions of intended use.		
STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED These products are solid articles and are not subject to leaks or spills.				
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES				
APPEARANCE/ ODOR Amidextrous, Beaded Cuff, Micro-textured, Chlorinated, Powder Free, Aqua Blue.				
DIMENSION	X-SMALL	SMALL	MEDIUM	LARGE
Length (mm)	240mm			
Width (mm)	76±3	84±3	94±3	105±3
THICKNESS (mm)- SINGLE WALL MEASUREMENT (same for all)				
Finger (mm)	0.05 ± 0.02			
Palm (mm)	0.05 ± 0.02			
TENSILE PROPERTIES		UNAGED	AGED	
Tensile Strength (Mpa)		Min. 18.0 MPa	Min. 16.0 MPa	
Ultimate Elongation (%)		Min 500%	Min 400%	
Elongation after Isopropanol immersion (%6)		Min 500%	N/A	
SECTION 10: STABILITY AND REACTIVITY				
BOILING POINT	VAPOR PRESSURE (mm Hg)	VAPOR DENSITY (air = 1)		
N/A	N/A	N/A		
SPECIFIC GRAVITY (water=1)	SOLUBILITY IN WATER	% VOLATILE BY VOLUME		
N/A	Insoluble	N/A		
EVAPORATION RATE	VISCOSITY			
N/A	N/A			
SECTION 11: TOXICOLOGICAL INFORMATION				
STABILITY Stable.		CONDITIONS TO AVOID Does not apply.		
INCOMPATIBILITY (MATERIALS TO AVOID) High polar solvent like methyl ethyl ketone, acetone.				
HAZARDOUS DECOMPOSITION PRODUCTS In a fire, these products may produce a black smoke. Carbon Dioxide, Carbon Monoxide, Oxides of Nitrogen, aromatic/aliphatic hydrocarbons.				
HAZARDOUS POLYMERIZATION Will not occur.				
SECTION 12: ECOLOGICAL INFORMATION				
N/A				
SECTION 13: DISPOSAL CONSIDERATION				
WASTE DISPOSAL METHOD Consult current local, state and federal regulations for proper disposal methods.				
SECTION 14: TRANSPORT INFORMATION				
N/A				
SECTION 15: REGULATORY INFORMATION				
N/A				
SECTION 16: OTHER INFORMATION				
RECOMMENDED USE AND RESTRICTION The Nitrile Powder Free Gloves is a Single Use device.				

EXAMINATION NITRILE GLOVE , POWDER FREE



STRONG
TEAR RESISTANCE & TOUGHNESS

Quality Standard

PRODUCTS

Thailand Industrial standard [TIS]
Thailand Food and Drug [FDA]
PPE [EU2016/425], EN374
MDR93/42/EEC , EN455
FDA USA, 510K
CE

FACTORY

ISO 9001
ISO 14001
ISO 13485
THAILAND FDA
GMP | HACCP

HOUSEHOLD DISPOSABLE GLOVES
SUPER THIN NITRILE GLOVES



Packaging

SIZING BOX CONTAIN



1 box = 100 pcs [50 pairs]

1 carton = 10 box [1000pcs, 500pairs]

PACKAGING & SHIPMENT



size : 7x11x22 cm [HxWxL]



1 BOX

WEIGHT

1 box = 100 pcs 620 g

1 box = 100 pcs 640 g

size M

size L



1 CARTON

PACKAGING

1 carton = 10 boxes = 1000 pcs = 500 pairs = 0.02 CBM

1 PALLET [1200X800 MM] = MAX 60 CARTON

WEIGHT [FULL PALLET] = 398 KG




HEIGHT = 1380 MM





1 CONTAINER

20' DC	14400 box =1440 carton/20' DC
40'DC	29700 box =2970 carton/40'DC
40'HC	32670 box =3267carton/40'HC

CONTAINER	SIZE	DIMENSION	
	20' Dry	L: 5.89 m	19'4"
		W: 2.34 m	7'8"
		H: 2.33 m	7'8"
	40' Dry	L: 12.01 m	39'5"
		W: 2.34 m	7'8"
		H: 2.36 m	7'9"
	40' Highcube	L: 12.01 m	39'5"
		W: 2.34 m	7'8"
		H: 2.66 m	8'9"

OUR PRODUCTION LINE / DAY [20HRS]

New high tech 2020
 Size machine : L160 m xW2.3m xH9.5m
 Size working : L170 m xW15m x H11m
 Height of building = 12 m

- Amount = 921,600 pcs/day[@20hr]
- Max capacity production = 9,216 box/day
- Max capacity production = **276,480 box /month [30days]**

8 - 9 CONTAINER A MONTH

PRODUCT SPECIFICATION

PRODUCT SPECIFICATION

DISPOSIBLE GLOVE - EXAMINATION NITRILE GLOVE , POWDER FREE

HS CODE 40151100



PRODUCT SPECIFICATION

- Protects against a wide range of chemicals as compared to natural rubber latex of the same thickness. Superior strength with better puncture resistance.
- Biologically Compatible.
- Softness and shape provides excellent comfort. Beaded cuff enhances donning and prevents roll back. High tensile strength and elongation.
- Ambidextrous and straight fingers.
Free from dirt marks, oil stains, embedded foreign particles, coagulum etc. Completely free of talc.
- Non Allergic.
- Polymer Coated for easy donning.
- Fully textured grip for great performance in all conditions.

Available Sizes	: XS , S , M , L ,XL
Packing	: 100 pcs./Box , 10Box/Carton
Dimension Inner Box	: W120 x L240 x H70mm.
Dimension Out Box	: W265 x L390 x H265mm.

PRODUCT SPECIFICATION

QUALITY STANDARDS

- Thailand Industrail standard [TIS]
- Thailand Food and Drug [FDA]
- PPE [EU2016/425], EN374
- MDR93/42/EEC , EN455
- FDA USA, 510K
- CE

GLOVE SIZES

XS, S, M, L

GLOVE COLOUR

- Blue

PRODUCT SPECIFICATIONS

- Material - Nitrile Glove Length - 240 mm +/- 5mm
- Weight - 3.0 to 5.0g +/- 0.5g per piece
- Surface - Finger Textured



PRODUCT SPECIFICATION



PRODUCTS

Thailand Industrail standard [TIS]
Thailand Food and Drug [FDA]
PPE [EU2016/425], EN374
MDR2017/745/EEC , EN455
FDA USA, 510K
CE

FACTORY

ISO 9001
ISO 13485
THAILAND FDA
GMP

PRODUCT SPECIFICATION

■ BEST NITRILE

DIMENSIONS

ISO 9001 Thailand Industrtrail standard [TIS]
ISO 13485 Thailand Food and Drug [FDA]
PPE [EU2016/425], EN374
CE
FDA

Size	Weight/PCS (Pinked)	Thickness@Palm Single Wall		Length (Median)		Width
	gm	mm	Mill	mm	in	mm
XS	3.5 ± 0.5g.	0.10	4.0	240mm		75 ± 3
S	3.5 ± 0.5g.	0.10	4.0	240mm		85 ± 3
M	3.5 ± 0.5g.	0.10	4.0	240mm		95 ± 3
L	3.5 ± 0.5g.	0.10	4.0	240mm		105 ± 3
XL	3.5 ± 0.5g.	0.10	4.0	240mm		115 ± 3

PRODUCT SPECIFICATION

■ BEST NITRILE

DIMENSIONS

ISO 9001 Thailand Industrail standard [TIS]
ISO 13485 Thailand Food and Drug [FDA]
PPE [EU2016/425], EN374
CE
FDA

Conformity : US.FDA21 CFR 177.2600 (Food Contact), Anti-bacteria

Defect : Dimension, Physical Properties, Holes

Definitions : Defects are imperfections which will result in the failure of the glove to perform its intended purposes - AQL 1.5

Properties to International Standard Test Methods

Property	Unit of Measure	Before Aging	After Aging
Tensile Strength	Mpa	≥ 10	≥ 7.5
Elongation @ Break	%	≥ 500	≥ 375

PRODUCT SPECIFICATION

Conformity : US.FDA21 CFR 177.2600 (Food Contact), Anti-bacteria

Defect : Dimension, Physical Properties, Holes

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Properties to International Standard Test Methods

Property	Unit of Measure	Before Aging	After Aging
Tensile Strength	Mpa	≥ 10	≥ 7.5
Elongation @ Break	%	≥ 500	≥ 375

PRODUCT SPECIFICATION

General Information

- Shelf Life : 3Years in cool, covered condition, exterior exposure to direct sunlight will reduce Shelf Life and will result in fading, discoloration and cracking
- Caution : 1) This product contain natural rubber latex which may cause allergic reaction in some individuals.
- 2) Not applicable for electrical use, protecting ionizing radiation, flames and Temperature at minus or over 100 degrees C.



เบอร์ 1056-2556



ISO 374-5:2016

ISO 374-1:2016/Type B



VIRUS



PT

GMP
CERTIFIED

POWDER
FREE

AQL
1,5



MEDICAL USA EXAMINATION GLOVE PACKAGING DESIGN

■ **MODEL : BEST GLOVE-NITRILE [USA]**

TYPE : NON-STERILE GLOVE
 WEIGHT : 3.5 G LENGTH : 240 MM
 COLOR : SKY BLUE



Quality Standard

PRODUCTS

FDA USA, 510K
 ASTM D 6319-2010
 CE

FACTORY

ISO 9001
 ISO 13485

Average M size

Weight
3.5 G

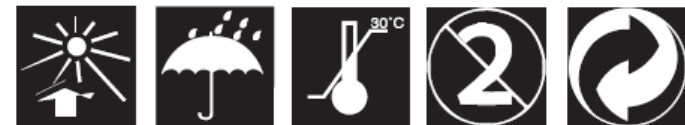
Length
240mm

100
 PCS/ชิ้น
 (By weight/โดยน้ำหนัก)

10
 BOX/กล่อง
 CARTON/ลัง

SIZE

XS
 S
 M
 L
 XL



SINGLE USE



Quality Standard

PRODUCTS

FDA USA, 510K

ASTM D 6319-2010

CE

FACTORY

ISO 9001

ISO 13485



EXAMINATION NITRILE GLOVE , POWDER FREE

MODEL : BEST GLOVE-NITRILE [USA]

TYPE : NON-STERILE GLOVE
 WEIGHT : 3.5 G LENGTH : 240 MM
 COLOR : SKY BLUE



HOSPITAL



DENTAL



DOCTOR



OPERATING ROOM



CLINIC



HEALTH CARE



EXAMINATION ROOM



PLASTIC SURGERY



MADE IN THAILAND

Quality Standard

PRODUCTS

FDA USA, 510K
 ASTM D 6319-2010
 CE

FACTORY

ISO 9001
 ISO 13485



ASTM
 D 6319-2010

AQL
 1,5





DURABLE



WATERPROOF



TEAR-PROOF



REPELS GREASE



WASHABLE



FADE RESISTANT



HIGH/LOW TEMPS



RECYCLABLE

EXAMINATION GLOVES SUPER THIN NITRILE GLOVES



ベストセーフ

BESTSAFE

BESTSAFE GLOVE CO.,LTD



MORE COMFORT & STRONGER THAN OTHER 50 %

**100 % NITRILE TYPE NON STERILE
WITH POWDER FREE**

For all purpose, laboratory, electronic
Prevention : liquid, acid- base, some chemical and
solvent

OUR MACHINE PRODUCTION



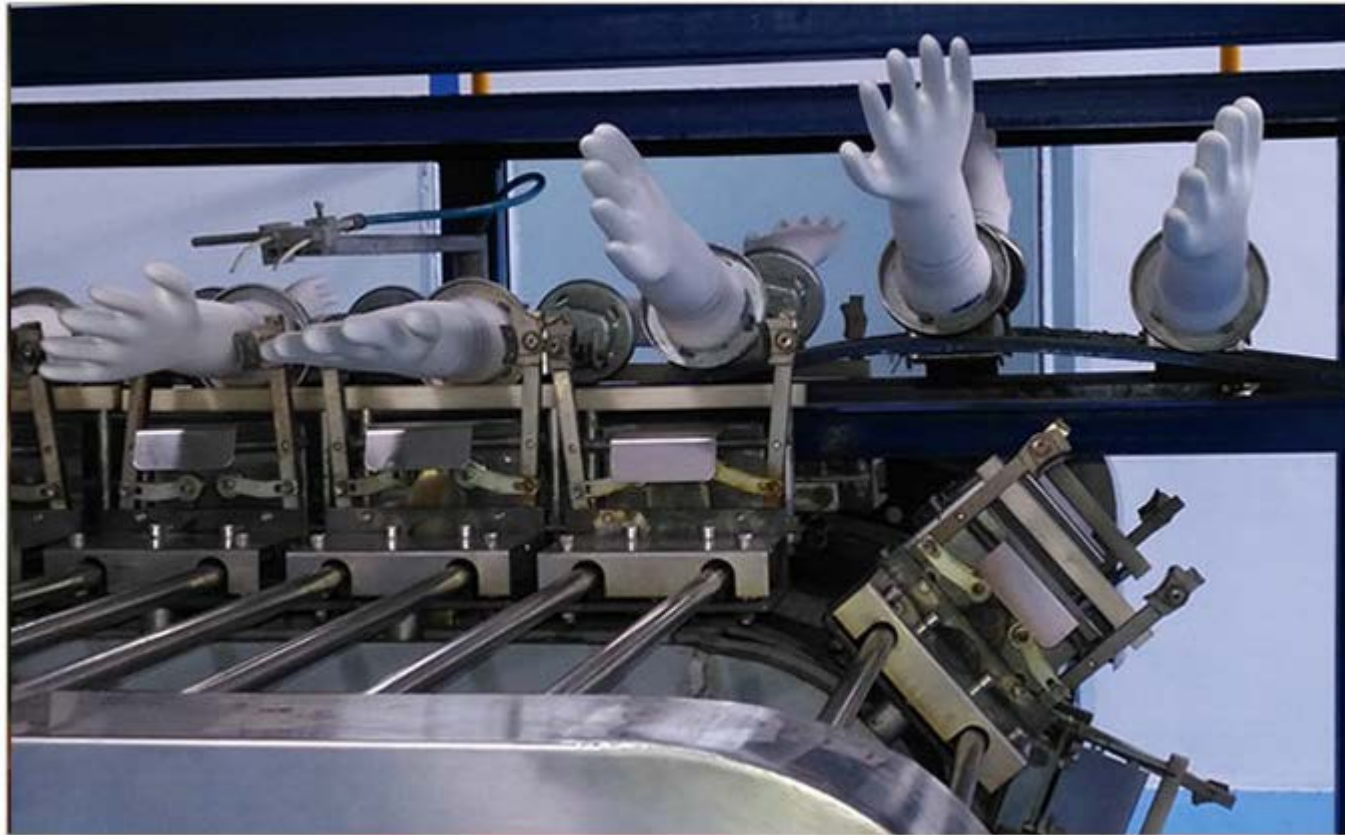
OUR MACHINE PRODUCTION



OUR MACHINE PRODUCTION



OUR MACHINE PRODUCTION



In progress



ISO 9001:2000

**CERTIFICATES &
AWARDS**

IN PROGRESS



รับรองการบริหารงานคุณภาพ

ISO 13485

bsi.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Holds Certificate No:

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

The manufacture of natural rubber latex and nitrile examination gloves for medical use.

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2006-11-24

Effective Date: 2019-07-29

Latest Revision Date: 2019-07-08

Expiry Date: 2022-07-29

Page: 1 of 1



...making excellence a habit.™

This certificate is issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +603 2242 4211.
Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization.
This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



CERTIFICATES & AWARDS

IN PROGRESS

รับรองระบบบริหารคุณภาพสำหรับการผลิตเครื่องมือแพทย์

MEDICAL Management system

ISO IEC 17025

CERTIFICATES & AWARDS

IN PROGRESS

BRITISH STANDARD

General requirements for the competence of testing and calibration laboratories

BS EN
ISO/IEC
17025:2005
*Incorporating
Corrigendum No. 1*

The European Standard EN ISO/IEC 17025:2005 has the status of a
British Standard

ISO 91:00:00

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BSi
British Standards

รับรองมาตรฐานห้องปฏิบัติการ

GMP (Good Manufacturing Practice)

**CERTIFICATES &
AWARDS**

IN PROGRESS



รับรองระบบควบคุมและการผลิต

CE (Conformity European)

CE

CE

ASTM D3578



CERTIFICATES & AWARDS

IN PROGRESS

รับรองมาตรฐาน ถังมือสำหรับการตรวจวินิจฉัย
ทางการแพทย์ประเทศสหรัฐอเมริกา

สำหรับยางธรรมชาติ

ASTM D6319

CERTIFICATES & AWARDS

IN PROGRESS



รับรองมาตรฐาน ถุงมือสำหรับการตรวจวินิจฉัย
ทางการแพทย์ประเทศสหรัฐอเมริกา

สำหรับยางสังเคราะห์

อีย. QUALITY AWARD

**CERTIFICATES &
AWARDS**

IN PROGRESS



สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข

อาหารและยา (ประเทศไทย)

FDA. QUALITY AWARD



CERTIFICATES & AWARDS

DISPOSSABLE GLOVE

US. FDA



FDA. QUALITY AWARD




 2020

CERTIFICATE OF REGISTRATION

This certifies that:
BESTSAFE GLOVE CO.,LTD
 52/43 Watkodhin-Kaophai Rd. T.Tubma
 A.Muang Rayong Rayong, TH 21000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	10077250
Device Classification Name:	PATIENT EXAMINATION GLOVE
Product Code:	FMC
Regulation Number:	880.6250
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

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 info@registrarcorp.com • www.registrarcorp.com

David Leonard
 Executive Director
 Registrar Corp
 Dated: August 24, 2020

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 2020

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 52/43 Watkodhin-Kaophai Rd. T.Tubma
 A.Muang Rayong Rayong, TH 21000

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	10077250
Device Classification Name:	LATEX PATIENT EXAMINATION GLOVE
Product Code:	LNY
Regulation Number:	880.6250
Official Correspondent and U.S. Agent:	Registrar Corp 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Leonard
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 Dated: August 24, 2020

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David Leonard
 Executive Director
 Registrar Corp
 Dated: August 24, 2020

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Establishment Registration & Device Listing

FDA Home Medical Devices Databases



1 result found for **Establishment Registration**
or **Business Trade Name** : *bestsafe*

[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
BESTSAFE GLOVE CO.,LTD THAILAND	No number listed	2020
<ul style="list-style-type: none"> Latex Patient Examination Glove 		Manufacturer; Repackager/Relabeler
<ul style="list-style-type: none"> Polymer Patient Examination Glove 		Manufacturer; Repackager/Relabeler
<ul style="list-style-type: none"> Patient Examination Glove 		Manufacturer; Repackager/Relabeler

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Page Last Updated: 09/14/2020

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FDA. QUALITY AWARD

**CERTIFICATES & AWARDS
EXAMINATION GLOVE**

IN PROGRESS



510(k)

US- FDA

US. FDA – 510 K

Re:

Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile,
Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile,
Tested for Use with Chemotherapy Drugs and Fentanyl Citrate
Powder Free Nitrile Patient Examination Glove, Black Colored, Non-Sterile,
Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Regulation Number: 21 CFR 880.6250

Regulation Name: Non-Powdered Patient Examination Glove

Regulatory Class: Class I

Product Code: LZA, LZC, QDO

Dated: -

Received:

Dear Cho Fong:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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



510(k)

US- FDA

IN PROGRESS

FDA. QUALITY AWARD

CERTIFICATES & AWARDS EXAMINATION GLOVE

EN455-1,
EN455-2,
EN455-3

Products



TÜVRheinland®
Precisely Right.

Report No.: 242122424-01 Page 1 of 7

Client: BESTSAFE GLOVE CO., LTD.
52/43 Watkodhin-Kaopai Rd., T. Tubma, A. Muang, Rayong 21000 Thailand

Identification/ Model No(s): Non-Sterile Nitrile Latex Examination Gloves
BEST GLOVE - NITRILE

Sample Receiving date: 2020-08-26

Testing Period: 2020-08-26 to 2020-09-11

Delivery condition: Apparent good, Samples tested as received

Test Specification:

- EN 455-1: 2000: Requirements for freedom from holes
- EN 455-2: 2015: Physical properties test;
 - Dimension test
 - Force at break test
- EN 455-3: 2015 (E), Annex A : Proteins extraction by aqueous

Test result:

PASS

PASS

PASS

Refer to result page

For and on behalf of
TÜV Rheinland Thailand Ltd.



2020-09-11

Wilawan Sriprom / Manager

Date

Name/Position

*Test result is drawn according to the kind and extent of tests performed.
This test report relates to the above mentioned Test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.*

TÜV Rheinland Thailand Ltd. - Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1,
Soi Chalokkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com - Web: www.tuv.com

FDA. QUALITY AWARD

Products



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Test Report No.: 242122424-01

Page 7 of 7

Sample photo:



- END -

CERTIFICATES & AWARDS EXAMINATION GLOVE


EN455-1,
EN455-2,
EN455-3

TUV Rheinland Thailand Ltd. - Global Technology Assessment Center Bangkok (GTAC BKK) Ladkrabang Industrial Estate 123/1,
Soi Chalokkung 31, Lamplatew, Ladkrabang, Bangkok 10520 Thailand
Tel.: +66 (0) 2326-1333 Fax.: +66 (0) 2326-1334-5 Email: info@tha.tuv.com Web: www.tuv.com

FDA. QUALITY AWARD IN PROGRESS

CERTIFICATES & AWARDS DISPOSABLE GLOVE

EN -374



Issued to:
Kossan International Sdn Bhd
Wisma Kossan, Lot 782
Jalan Sungai Putus, Off Batu 3 3/4
Jalan Kapar
42100 Kiang
Selangor Darul Ehsan
Malaysia

Notified Body: 2777 SATRA customer number: P1343

EU Type-Examination Certificate

Certificate number: 2777/10015-03/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	Description
PFN	Disposable powder free nitrile glove available in white, blue and indigo. Non-Sterile
Sizes: 5/6 (XS) to 10/11 (XXL)	

Classification:

EN ISO 374-1: 2016 (Type B)	Level	EN374-4: 2013 Degradation %
*4% Chlorhexidine Digluconate	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
10% Acetic Acid	4	68.7
5% Ethidium Bromide	6	3.4
37% Formaldehyde (T)	3	5.0
65% Nitric Acid (M)	0	97.6
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
30% Hydrogen Peroxide (P)	2	22.8
1.5% Methanol in water	6	21.9
70% Isopropanol	0	62.2
35% Ethanol	0	38.8
99% Acetic Acid (N)	0	93.0
25% Ammonium Hydroxide (O)	1	-52.0
3% Povidone-iodine	6	33.7
10% Sodium Percarbonate	6	15.4

* Permeation rate 7µg/cm²/min


EN ISO 374-5: 2016	
Protection against Bacteria & Fungi	Pass
Protection against viruses	Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2006; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0216113/1327/SMcD/RS, SPC0216113/1327, PRC0250570/1640/SPT, CHM0248297/1630/ENE, CHM0248297/1630/END/Issue 2, CHM0257198/1719/SMcD/A, CHM0257198/1719/SMcD/B, CHM0257198/1719/SMcD/C, CHM0257198/1719/SMcD/D


Signed on behalf of SATRA:

Date first issued: 21/04/2018
Date of issue: 25/03/2019




Hannah Coe

Expiry date: 21/04/2023


Quincey Brown

Page 1 of 2

SATRA Technology Europe Limited, Brackdown Business Park, Conner, D15YNP, Republic of Ireland.



ベストセーフ
BESTSAFE
BESTSAFE GLOVE CO.,LTD

SGS APPROVED

- Before shipment

