PPE GROUP

VGlove®

PPE GROUP

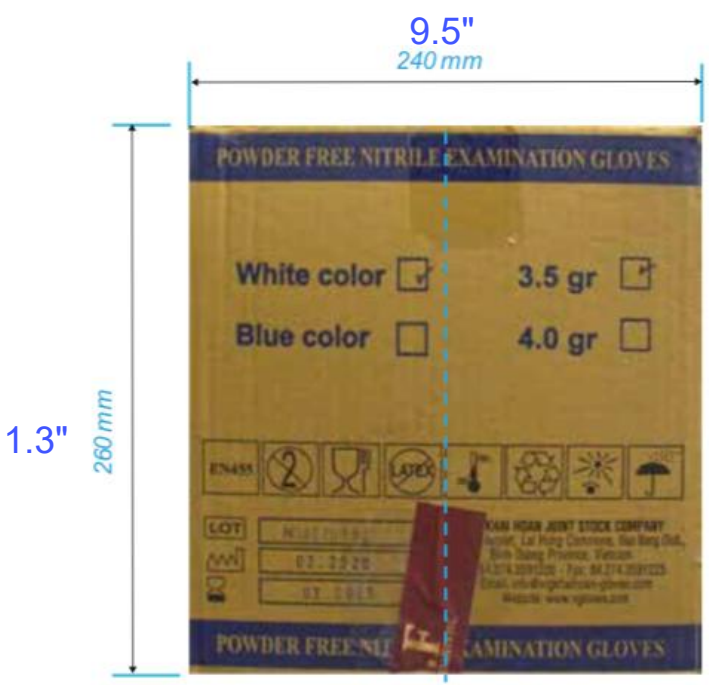

NITRILE
Powder Free NITRILE examination Gloves
VGlove
Detergent.vn
VGlove®
Powder Free Nitrile Examination Gloves
Latex Free. Ambidextrous. Non-Sterile. Single-Use.
Finger Tip Textured
L
Large
NITRILE
VGlove - Protect Your Life
100 by weight


NITRILE
VGlove
M
VG\ove ®
CONG TY CO PHAN VRG KHÁI HOÀN
Sản xuất tại Việt Nam
LOT

10 Boxes Per Carton

QUY CÁCH THÙNG CARTON
Kích thước: 360 mm x 260 mm x 240mm
Trọng lượng: ~4kg/ Thùng

Số lượng 10 hộp / thùng



NITRILE GLOVES

POWDER FREE

Functional Benefits

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

Product Specifications

Material	Synthetic Nitrile latex.
Type	Non-Sterile Powder-Free. Ambidextrous; Finger Tip Textured; Beaded Cuff; White or Colored (Blue, Light Blue, …)
Quality Standards	Conforms to ASTM D6319 Manufactured under ISO9001: 2008, ISO 13485:2003. ISO 22000:2005 Quality Management System. Manufactured from 100% nitrile (Acrylonitrile-Butadiene)
Gloves Size	Extra-small, Small, Medium, Large, Extra-large. Marked in the check box on the shipping carton with black ink.
Storage	Store in a dry and cool place, the temperature not higher than 38°C.
Shelf-fife	3 years from the date of manufacturing.

PHYSICAL DIMENSIONS (THIS IS OUR RUNNIG SPEC & WE CAN ADJUST THE SIZES BASED ON CUSTOMER SPEC)

DIMENSIONS	Standards	
	VRG KHAI HOAN	ASTM D6319
Length (mm)	230 min	220 min (XS, S) 230 min (M, L, XL)
Width (mm)	75 ± 5 (XS) 85 ± 5 (S) 95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)	70 ± 10 (XS) 80 ± 10 (S) 95 ± 10 (M) 110 ± 10 (L) 120 ± 10 (XL)
Thickness-	Fingers : 0. 08 mm min	Fingers : 0.050 mm min
Single wall (mm)	Palm : 0.06 mm min	Palm : 0.05 mm min

PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

Tensile	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min Elongation at break (%) Before aging: 600% min After aging: 500% min	Tensile strength (MPA) Before aging: 14Mpa min After aging: 14Mpa min Elongation at break (%) Before aging: 500% min After aging: 400% min
Powder Content	2 mg/glove maximum	
Protein Content	Free Protein	

HS CODE: 40151900

PPE GROUP

bsi.

By Royal Charter

Certificate of _Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2005

This is to certify that:

[redacted]

Holds Certificate Number: **FSMS 552546**

and operates a Food Safety Management System which complies with the requirements of ISO 22000:2005 for the following scope:

The manufacture and distribution of:
Non-sterile, powder, powder free natural latex examination gloves;
Non-sterile, powder free nitrile examination gloves.

Category: I

For and on behalf of BS!: Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: **09/10/2009**
Latest Revision Date: **14/07/2018**

Effective Date: **09/10/2018**
Expiry Date: **18/06/2021**

-making excellence a habiC

bsi.

By Royal Cr

Giay Chu'ng Nh n

H• THONG QUAN LY AN TOAN THI/C PHAM - ISO 22000:2005

Giu' giay chu'ng nhan so: **FSMS 552546**

va thu'c hi•n He Thong Quan Ly An Toan Thu'c Pham phu hdp voi cac yeu cau cua ISO 22000:2005 cha ph9m vi:

San xuat va phan phoi:
Gang tay cao su thien nhien y te khong ti•t trung co bc;,t va khong bc;,t;
Gang tay nitrile y te khong ti•t trung khong bc;,t.

Phan lo•i: I

Dai dien cha t•p doan BS!: Chris Cheung, Phi,! Trach Su' Tuan Thu & Rui Ro Chau A Thai Binh

Ngay dang ky dau tien: **09/10/2009**
Ngay su'a doi sau cung: **14/07/2018**

Ngay hi•u lu'c: **09/10/20U**
Ngay het hi•u lu'c: **18/06/21**

-making excellence a r

bsi.

By Royal Charter

Certificate of Registration

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that:

[redacted]

Holds Certificate Number: **BSIVN 1313/2019**

and operates a Good Manufacturing Pratice which complies with the requirements of GMP-HACCP (CAC/RCP 1-1969, Rev.4-2003) the following scope:

The manufacture and distribution of:
- Non-sterile, powder, powder free natural latex examination gloves.
- Non-sterile, powder free nitrile examination gloves.

For and on behalf of BSI: Le Duyen Anh, Managing Director Vietnam

Original Registration Date: **10/06/2019**
Effective Date: **10/06/2019**
Latest Revision Date: **10/06/2019**
Expiry Date: **09/06/2022**

bsi.

By Royal Charter

Giấy Chứng Nhận

THỰC HÀNH SẢN XUẤT TỐT – GMP

Giữ giấy chứng nhận số: **BSIVN 1313/2019**

và thực hiện Thực Hành Sản Xuất Tốt phù hợp với các yêu cầu của GMP-HACCP (CAC/RCP 1-1969, Rev.4-2003) cho phạm vi:

Sản xuất và phân phối:
- Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột.
- Găng tay nitrile y tế không tiệt trùng, không bột.

Đại diện cho tập đoàn BSI: *Tổng Giám đốc BSI Việt Nam, Ông Lê Duyên Anh*

Ngày đăng ký đầu tiên: **10/06/2019**
Ngày hiệu lực: **10/06/2019**
Ngày sửa đổi sau cùng: **10/06/2019**
Ngày hết hiệu lực: **09/06/2022**

FDA CONFIRMATION OF LZA

accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=645691&lpcd=LZA

ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

Proprietary Name:	Powder Free Nitrile Examination Glove
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	[redacted]
Registered Establishment Number:	
Premarket Submission Number:	
Owner/Operator:	
Owner/Operator Number:	10025798
Establishment Operations:	Manufacturer

Page Last Updated: 05/04/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies

Establishment Registration & Device Listing

1 result found for **Owner Operator Name :**
Kha/ hoen Joint Stock Company

New Search

Establishment Name	Regiatration Number	Current Registration Yr
[redacted]	3007048214	2020
• Latex Patient Examination Glove - Powder Free Latex Examination Glove		Manufacturer
• EQlY.roerPatient.Examination.Glove_-.Powder.free.Nitrile Examination Glove		Manufacturer

Can't find what you're looking for? Try a new search

Page Last Updated: 04/27/2020

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Language Assistance Available: Espanol | 體cp)t | Tieng Vi$t | <>i | Tagalog | PyccKv1 | [illegible] | Kreyc Ayisyen | Fran9ais | Polski | Portugues | Italiano | Deutsch | B*ig | U'--"Ju | English

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph, 1-888-INFO-FDA (1-888-463-6332)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Servicl

Food and Drug Adm
10903 New Hampsh
Document Conirol R
Spring, MD 2t

, Silver

[redacted]

Re: K092681
Trade/Device Name: Powdered Latex Examination Gloves (Non-Cplored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: J
de: LYY

[redacted]

Dear Mr. Lim:

We have reviewed your Section 51O(k) preinarket notification of intent to market the di referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices markel 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 provisior the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a prem: approval application(PMA). You may, therefore, market the device, subject to the gen 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 adulteraticm. Please note: CDRH d not evaluate information· related to contract liability warranties. We remind you, howe, that device labeling must be truthful and not misleading.

If your device. is classified (see above) into either class II (Special Controls) or class m (PMA), it may be subject to additional controls. Existing major regulations affecting yi device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDAmay publish further announcements concerning your device in the Feder 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, burnot limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part:801); medical device reporting (repmting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (2I 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 go to http://www.fda.gov/AboutFDNCentersOffices/CDRH/CDRHOffices/ucm I I5809.him for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (2I 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 PostinarketSurveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance 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 yours,

-\bl
Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, Generlil Hospital,
Infection Control and Dental Devices
Office ofDevice Evaluation
Center for. Devices and
Radiological Health

Enclosure

Trong quá lrlnh hru hành sản phi m don vị co tnlcb nbient:
In the products •circulation and busi11tJs actfritits, it is rtquired to strictly obty the follow·ing obligations:

J. Phải chịu trách nhiệm về chất Jượng sản phLm đã ding k f
Havtfull rtspo11sibiJity 011 quality of the product rtgistertd.

2. Chấp hành đầy đủ các quy djnh về quản lf lrlng thiết bị y tt CUA Bộ y tế•
Conform to the S.R. Vie111am Ministry of Health's rtgula1ions or, managemen tt of medical equipme111.

3. Thong l».o cho SQ Y tế lM1c 30 ngày trong c trường hợp sau:
Inform to the Miriistry of lf,ea/th i11 advan u (10 days) in the following cases:
- Thayd6idịa chi(Anychange o/Manufacturer's address)
– Mọi sl,lthay d6i liên quan đến sản phlm (Anyd1ange ofthe registered prodllcl)
– Tách, sáp nhập, đổi tên hoặc ch4in di.it hoạt dQng sản xuất kinh doanh (An)' splir, merge, re11ame and interruption ofthe product's prod,1ction and bussiness)

4. Giấy chứng nhận này c6 giá uj 03 (ba) nam k rừ ngày k9. Trước khi hết hạn 30 (ba mươi) ngày•don vị plw llm lhu l\lc xin gia bạn đăng ký n!u vẫn tiếp tục lưu hành sảnpbb,cren.
This Certification has o ,alidity of three (OJ) years 1tartillg from the signing date. Before iis expiration dart oftl,irty (JO) doys, ii is rtquired to renew the validity ofurtificotion •fthe prod11ct is conrin11ing circulotio11 in \lietnam.

TL. BỘ TRƯỞNG
VỤ TRƯỞNG
VỤ TRANG THIẾT BỊ - CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL EQUIPMENT & CONSTRUCTION
Director

Nguyễn Minh Tuấn

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAMf
SOCIALIST REPUBLIC OF VIETNAM

BỘ Y TẾ
MINISTRY OF HEALTH

GIẤY CHỨNG NHẬN

DANG KY LUU HANH SAN PHAM TRANG THIIT BI YT SAN XU.(rr , VI NAM

CERTIFICATE

REGISTRATION FOR CIRCULATION OF
MEDICAL DEVICE MANUFACTURING IN VIETNAM

B◊ \' TẾ
Số (No) 15/1.011/BYf-TB-CT

H l NQi, ngly (dale): 06/5/1.011

GIẤY CHỨNG NHẬN
ĐĂNG KÝ LƯU HÀNH SẢN PHẨM TRANG THIẾT BỊ Y TẾ SẢN XUẤT TẠI VIỆT NAM

CERTIFICATE
REGISTRATION FOR CIRCULATION OF MEDICAL DEVICE MANUFACTURING IN VIETNAM

- Cln ell' LU41 W t lUQng sin flh',n, blog ti<» ngly 21/11/1.007.
  Bastd on Law on Quality ofproducts and goods dattd Novt r 21, 2007.
- O n ell' Tuong n, số 07/1.002/IT-BYf ngày '30/5/1.002 cua **BQ Y** *tt* hoong *din* ding *ty* luu **hmh** *s1n* flhm Trang *thitt bi* y *tt.*
  Bastd on Circular Ulltr 0712002/TT-BYf dattd May 30, 2002 of tht Ministry of Health on guiding for circulation rtgistration of !Mdical dn·ict.
- X t h6 sơ n don nghi cip s6 ding *ky* luu **hmh** *s1n* flhm cua *don* v,.
  Having examination of documentation and application ltttrfor drculation oftMdical dti·ict submitttd by tht applicant.

BỘ y TẾ CHỨNG NHẬN
MINISTRY OF HEALTH CERTIFIES THAT

HAS A PERMISSION TO CIRCULATE THE FOLLOWING MEDICAL DEVICE IN VIETNAM

- Ten sản flh',n: GĂNG TAY CAO SU Y 1't
  (Name of the product)
- Ky *mi hiu s1n* flh',n: KHPPEX, KHPFEX, ICHPPSS
  (Model and Serial number)
- Tau chuin cOng b ộ: ASTM D 3578-OS
  (C.onfonn to the Slandards of)
- Số ding ky luu hmh dUQC cip: IS/2011/BYT-TB-CT
  (RcgiSlered number)