

Nitrile & Latex Gloves

2020.06.09



PRODUCT(Nitrile)

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 Coloured (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-life	3 years from the date of manufacturing.

PHYSICAL DIMENSIONS

DIMENSIONS	Standards	
	VRG KHAI HOAN	ASTM D6319
Length (mm)	230 min	230 min (M, L, XL)
Width (mm)	95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)	95 ± 10 (M) 110 ± 10 (L) 120 ± 10 (XL)
Thickness- Single wall (mm)	Fingers : 0.08 mm min Palm : 0.06 mm min	Fingers : 0.050 mm min Palm : 0.05 mm min

PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

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

Chlorinated Online Powder Free Latex Examination Gloves

Functional Benefits

- Superior tensile strength for extraordinary resiliency
- Superior puncture & tear resistance properties.
- Protection from unwanted & dangerous substances
- Softness provides superior comfort and natural fit. Fit more comfortably, reduced hand fatigue & respiration.
- Beaded cuff makes easy donning and guards against tearing.
- Smooth gloves donning surface provides a more natural feel.
- Powder free to eliminate powder – induced irritation & dermatitis to user
- Low level of extractable protein & chemical residue, hence lower incidence of allergic reactions.

Product Specifications

Material	Natural high grade latex.
Design & Features	Ambidextrous, beaded cuff, smooth or fully palm textured.
Quality Standards	ASTM D3578 (05) standards Under GMP practice.
Gloves Size	Small, Medium, Large, Extra-large.
Colour	Natural
Brand	Vglove

PHYSICAL DIMENSIONS

Length (mm)	240 mm	
Width (mm)	95 ± 3 (M) 105 ± 3 (L) > 110 (XL)	
Thickness	Measurement Location	Single Wall (mm)
	Finger tip (at 13 ± 3mm from the extreme tip)	min 0.01
	Palm (at centre of palm)	min 0.01

PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

Tensile	<p>Tensile strength (MPA) Before aging: 18Mpa min After aging: 14Mpa min</p> <p>Elongation at break (%) Before aging: 650% min After aging: 500% min</p>
Powder Content	Powder content ≤ 2mg per gloves
Protein Level	Aqueous extractable protein : 50ug/dm ² or less with label claim

IMAGE (Nitrile)

Date of shooting April 29, 2020



<Item>



<Pack>



<Box>

Date of shooting April 29, 2020



<Item, Pack>



<Box>



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Establishment Registration & Device Listing

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Establishment:
 VRG KHAI HOAN JOINT STOCK COMPANY
 Cau Sat Hamlet, Lai Hung Commune
 Bau Bang District Binh Duong, VN 084
Registration Number: 3007048214
FEI Number: 3007048214
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
[VRG Khai Hoan Joint Stock Company](#)
 Cau Sat Hamlet, Lai Hung Commune
 Bau Bang District, Binh Duong VN 0000
Owner/Operator Number: 10025798

Official Correspondent:
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Phone: 084-650-591220

US Agent:
 N/A
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* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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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: [VRG KHAI HOAN JOINT STOCK COMPANY](#)
Registered Establishment Number: 3007048214
Premarket Submission Number: K151208
Owner/Operator: [VRG Khai Hoan Joint Stock Company](#)
Owner/Operator Number: 10025798
Establishment Operations: Manufacturer

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Establishment Name	Registration Number	Current Registration Yr
VRG KHAI HOAN JOINT STOCK COMPANY VIET NAM	3007048214	2020
<ul style="list-style-type: none"> • Latex Patient Examination Glove - Powder Free Latex Examination Glove • Polymer Patient Examination Glove - Powder Free Nitrile Examination Glove 		Manufacturer

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