SUPPLY DISTRIBUTION RECORD

PRODUCTS

MASKS
PROTECTIVE EQUIPMENT
MEDICAL GLOVES

2020

Meeting **ISO 9001:2015** and **ISO 13485:2016** standards,

Holding Certificate **510K approved by FDA for goods exportation to the US**,

Meeting **CE Marking** standard for goods exportation to **Europe**,

Holding Certificate **QUATEST3** issued by the Ministry of Health

VRG KHAI HOAN JOINT STOCK COMPANY

PRODUCT TYPES

- POWDER AND POWDER-FREE NITRILE EXAMINATION GLOVES
- POWDER AND POWDER-FREE LATEX EXAMINATION GLOVES
- STERILE LATEX SURGICAL GLOVES

POWDER LATEX EXAMINATION GLOVES

PRODUCT DETAILS

VGLOVE

Product	**Powdered latex examination gloves**		
Material	Natural Latex		
Powder content	≤10mg/dm^2		
Protein level	Aqueous extractable protein: 20µg/dm^2 or less than this claimed level		
Color	Natural rubber color		
Features	Ambidextrous, Beaded Cuff, Smooth glove surface or textured palm		
Packing	100 gloves/box, 10 boxes/carton		
Brand	VGLOVE		
Physical dimensions	Size range	Palm width (mm)	Length (mm)
	Extra small	< 80	min 240
	Small	85 ± 3	min 240
	Medium	95 ± 3	min 240
	Large	105 ± 3	min 240
	Extra large	> 110	min 240
Thickness	Measurement location		Single-layer (mm)
	Fingertips (13 ± 3mm from the extreme tip)		min 0.01
	Palm (at the center of the palm)		min 0.01
Mechanical properties	Before ageing		After ageing
	(70 ± 2oC within 7 days)		
	Tensile strength	min 18.0	min 14.0
	Elongation (%)	min 650	min 500
Functions and Effects	- Avoid direct contact with unwanted toxic and hazardous substances		
	- Easy to wear and difficult to curl when donning		

POWDER LATEX EXAMINATION GLOVES

PRODUCT IMAGES

VGLOVE

Back

FDA 510K

QUATEST3

Top/Bottom

Actual product

Front

Left/Right

POWDER-FREE NITRILE EXAMINATION GLOVES

PRODUCT DETAILS

VGLOVE

Material	Nitrile
Type	Powder-free, non-sterile
	Ambidextrous, Finger Tip Textured; Beaded Cuff White or blue (Blue, Light Blue)
Quality standards	Conforms to ASTM D6319
	Manufactured under ISO 9001:2008; ISO 13485:2003, ISO 22000:2005 quality management system
	Manufactured from 100% nitrile (Acrylonitrile-Butadiene)
Glove sizes	Extra-small, Small, Medium, Large, Extra-Large.
	Marked in the checkbox on the shipping carton with black ink.
Storage	Store in a cool and dry place, the temperature is below 30^{o}C
Shelf-life	3 years from the date of manufacturing

Physical 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)	70 ±10 (XS)
	85± 5 (S) 95±5 (M)	80±10 (S) 95±10 (M)
	105±5 (L)	110±10(L)
	115 ± 5 (XL)	120±10(XL)
Thickness(mm)	Fingers: 0. 08 mm min	Fingers: 0.05mm min
	Palm: 0.06 mm min	Palm: 0.05 mm min

POWDER-FREE NITRILE EXAMINATION GLOVES

PRODUCT DETAILS

VGLOVE

PHYSICAL AND CHEMICAL INDICATORS

Tensile	**Tensile strength (MPA)** Before ageing: 18 Mpa min After ageing: 20 Mpa min **Elongation at break (%)** Before ageing: 600% min After ageing: 500% min	**Tensile strength (MPA)** Before ageing: 14 Mpa min After ageing: 24 Mpa min **Elongation at break (%)** Before ageing: 500% min After ageing: 400% min
Powder content	2mg/1 glove maximum	
Protein content	Free Protein	

PRODUCT IMAGES

Carton packing

Quantity: 10 boxes/carton

Physical dimensions: 360mm x 260mm x 240 mm

Weight: ~ 4kg/carton

POWDER FREE NITRILE EXAMINATION GLOVES

PRODUCT IMAGES

VGLOVE

Front

-Powder-free nitrile examination gloves

-Powder-free, Ambidextrous, non-sterile, Fingertip textured

-Single use

-100 gloves

Top/Bottom

Powder-free nitrile examination gloves

100 gloves

Back

VRG KHAI HOAN JOINT STOCK COMPANY

Cau Sat Hamlet,

Lai Hung Commune, Bau Bang District,

Binh Duong Province

Vietnam

Tel: (84.274) 3591220

Email: info@vrgkhaihoan-gloves.com

Website: www. vgloves.com/

Manufactured in Vietnam

Pink color 3.5g

White color 4g

Main property: artificial rubber

Storage

Store in a cool and dry place,

Avoid direct sunlight and thermal radiation resource,

The temperature is below 30^{o}C.

Warning: Should not use directly to radiation light

Left/Right

Powder-free

Ambidextrous

Non-sterile,

Single use

100 gloves

STERILE LATEX EXAMINATION GLOVES

PRODUCT DETAILS

VGLOVE

Product	Sterile surgical latex gloves, sterilized by E.O gas		
Material	Natural high-grade latex		
Powder content	≤10 mg/dm^2		
Protein level	≤200µg/glove		
Color	Natural latex white		
Features	Hand shaped curves, distinguishing left hand and right hand with beaded cuff		
Packing	1 pair/bag, 50 bags/box, 4 boxes/carton		
Brand	VGLOVE		
Physical dimensions	Size	Palm Width (mm)	Length (mm)
	6	77 ± 5	280 ±5
	6.5	83 ± 5	280 ±5
	7	89 ± 5	280 ±5
	7.5	95 ± 5	280 ±5
	8	102 ±6	280 ±5
Thickness	0.10 mm		
Mechanical properties		**Before Ageing**	**After Ageing**
	Minimum breaking load (MPA)	21	16
	Minimum elongation at break time (%)	700	550
Weight (gam) Tolerance: ± 0.3gr	Size	6	7.0 ± 0.3gr
		6.5	8.0 ± 0.3gr
		7	9.0 ± 0.3gr
		7.5	10 ± 0.3gr
		8	11 ±0.3gr

STERILE LATEX SURGICAL GLOVES

PRODUCT DETAILS

VGLOVE

Functions and benefits	- Sterile surgical latex gloves are used during the examination, treatment diagnosis and surgical operation to protect against disease transmission between patients and users of surgical gloves.
	- Distinguishing left and right hand, softness provides superior comfort and naturally fit for its users. In addition, users will satisfy with the function of reducing hand sweet which causes uncomfortable feeling.
	- Smooth glove surface brings natural, comfortable feeling to users and makes it easier to operate. Also, beaded cuff makes easy donning and guards against tearing.
	- Powder content is in the permitted level – the factor causes itching and skin inflammation when using.
	- Protein and the chemical level of gloves are lowest to minimize skin allergies for users.
Evaluation standards	Under the US quality evaluation standards - ASTM D3578 (05), AQL 1.5

CARTON SPECIFICATIONS:

Physical dimensions: 580 mm x 300 mm x 450 mm

Box quantity: 8 boxes/carton

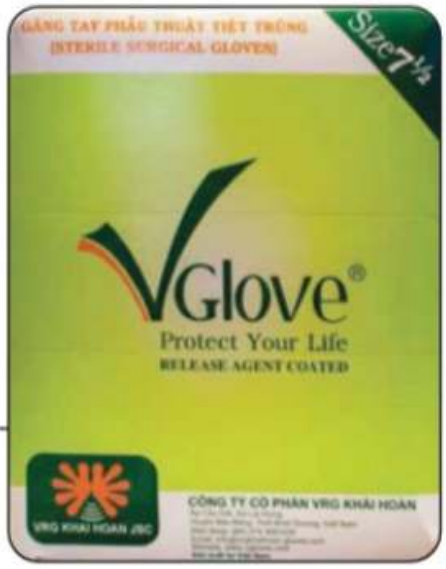
Weight: ~15kg/carton

STERILE SURGICAL LATEX GLOVES

PRODUCT DETAILS

VGLOVE

Left



Front/back

Right

Top/bottom

Actual product

CERTIFICATE

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province
Vietnam

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

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

Manufacture and distribution of
- Powder and powder-free non-sterile latex examination gloves
- Powder-free, non-sterile nitrile examination gloves.

For and on behalf of BSI: *(signed and sealed)*
Le Duyen Anh, Managing Director of BSI Vietnam

Original Registration Date: **June 10, 2019** Effective Date: **June 10, 2019**
Latest Revision Date: **June 10, 2019** Expiry Date: **June 9, 2022**

By Royal Charter

CERTIFICATE

QUALITY MANAGEMENT SYSTEM – ISO 9001:2015

This is to certify that **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province
Vietnam

Holds the Certificate Number **FM 548618**

and operates a Quality Management System which complies with the requirements of ISO 9001: 2015 for the following scope:

Manufacture and distribution of
- Powder and powder-free non-sterile latex examination gloves;
- Powder-free, non-sterile nitrile examination gloves.

For and on behalf of BSI: *(signed and sealed)*
Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: **June 1, 2009** Effective Date: **June 1, 2018**
Latest Revision Date: **May 30, 2018** Expiry Date: **May 31, 2021**

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bsi.

By Royal Charter

CERTIFICATE

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

This is to certify that **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province
Vietnam

Holds the Certificate Number **MD 548620**

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

Manufacture and distribution of
- Powder and powder-free non-sterile latex examination gloves
- Powder-free, non-sterile nitrile examination gloves.

For and on behalf of BSI: *(signed and sealed)*
Stewart Brian, Head of Compliance & Risk - Medical Devices

Original Registration Date: **May 18, 2009** Effective Date: **May 18, 2018**
Latest Revision Date: **May 2, 2018** Expiry Date: **May 17, 2021**

bsi. UKAS QUALITY MANAGEMENT 003

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By Royal Charter

CERTIFICATE

SOCIAL ACCOUNTABILITY INTERNATIONAL – SA 8000:2014

This is to certify that **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province
Vietnam

Holds the Certificate Number **SA 598117**

and operates a Social Accountability System which complies with the requirements of SA 8000:2014 for the following scope:

Manufacture and distribution of powered and powered-free latex examination gloves, nitrile examination gloves, including processes of receiving latex/nitrile materials, mixing, coagulating, vulcanizing, extracting, dipping corn/chlorine foam, drying, checking and packing.
External machining processes: None.
External contracting processes: None.

For and on behalf of BSI: *(signed and sealed)*
Venkataram Arabolu, Managing Director of BSI Group India

Original Registration Date: **November 19, 2013** Effective Date: **November 19, 2019**
Latest Revision Date: **November 11, 2019** Expiry Date: **November 11, 2022**

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PRODUCT'S CERTIFICATES

Australia | Canada | China | Japan | The Netherlands | United States

EMERGO EUROPE

26 May 2009

Mr. Terence Lim
Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong
Vietnam

Dear Terence:

I am writing to inform you that today, we have notified by registered mail the Dutch Competent Authority.

With this notification, Khai Hoan Joint Stock Company has met the requirements of Article 14 of the Medical Devices Directive, 93/42/EEC for the following devices:

- **Powder Examination Gloves**
- **Powder-Free Examination Gloves**

As of today and without any further notice from the respective Competent Authorities, Khai Hoan Joint Stock Company can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO

EmergoEurope.com

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299

PRODUCT'S CERTIFICATES

EMERGO EUROPE

CE Registration Certificate

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong Province
Vietnam

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received Medical Device Registrations on the following date:

26 May 2009
See attached product listing

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the Medical Devices fulfill the applicable requirements of Directive 93/42/EEC.

June 2009

Rene van de Zande
President & CEO
Emergo Europe

PRODUCT'S CERTIFICATES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-C
Silver Spring, MD 20993-0002

FEB 23 2010

Mr. Terence Lim
Quality Assurance Manager
Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune, Ben Cat District
Binh Duong Province
VIETNAM

Re: K092681
Trade/Device Name: Powdered Latex Examination Gloves (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: January 14, 2010
Received: January 19, 2010

Dear Mr. Lim:

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.

PRODUCT'S CERTIFICATES

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm 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 (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 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,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PRODUCT'S CERTIFICATES

SATRA TECHNOLOGY

Issued to:

VRG Khai Hoan JSC
Cau Sat Hamlet
Lai Hung Commune
Bau Bang District
Binh Duong Province
Vietnam

Notified Body: 2777

SATRA customer number: P1434

EU Type-Examination Certificate

Certificate number: 2777/11582-01/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:

PFNBR

Description:

Non-sterile powder free nitrile examination gloves

Sizes:

XS/6, S/7, M/8, L/9, XL/10

Classification:

EN ISO 374-1: 2016 / Type B	Level	EN ISO 374-4:2013 % Degradation
40% Sodium hydroxide (K)	6	-13.2
30% Hydrogen peroxide (P)	4	5.3
37% Formaldehyde (T)	6	4.6
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0225034/1420/2, SPC0225034/1420/SMcD/B, SPC0244727/1615, CHM0248775/1632/SMcD, CHM0272778/1827/LH, CHM0276386/1840/JH, SPC0244727/1615, SPC0273658/1830, CHM0273594/1830/LH/A, CHM0273594/1830/LH/B, CHM0273594/1830/LH/C
TUV: 7191169844-CHM17-01-RC

Signed on behalf of SATRA: Tara Saunders Austin Simmons

Date first issued: 23/11/2018
Date of issue: 23/11/2018

Expiry date: 23/11/2023

PRODUCT'S CERTIFICATES

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.

PRODUCT'S CERTIFICATES

KHAI HOAN JOINT STOCK COMPANY

Cau Sat Hamlet, Lai Hung Commune, Ben Cat District, Binh Duong Province, Vietnam

Indications for Use

Applicant : KHAI HOAN JOINT STOCK COMPANY

510(k) Number (if known): K092681

Device Name: POWDERED LATEX EXAMINATION GLOVES (NON-COLORED)

Indications for Use:

Powder Natural Rubber Latex Examination Gloves is a non-sterile, single use device intended for medical purposes that is worn on the hand of medical personnel to prevent contamination between the patient and examiner.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092681

PRODUCT'S CERTIFICATES

DIRECTORATE FOR STANDARDS, METROLOGY AND QUALITY

TECHNICAL CENTER FOR QUALITY MEASUREMENT STANDARDS 3

No.: 0710/QD-KT3

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

Ho Chi Minh City, May 4, 2019

DECISION

On granting product certificate

DIRECTOR OF TECHNICAL CENTER FOR QUALITY MEASUREMENT STANDARDS 3

Pursuant to the Decree No. 1668/QD-TDC dated August 26, 2014, of the DIRECTORATE FOR STANDARDS, METROLOGY AND QUALITY on promulgating the organization and operation charters of Technical Center for Quality Measurement Standards 3 (Technical Center 3);

Pursuant to the Circular No. 28/2012/TT-BKHCN dated December 12, 2012, of the Ministry of Science and Technology on stipulating the announcement of standard conformity, regulation conformity and evaluation methods of the conformity in accordance with technical standards, regulations and the Circular No. 02/2017/TT-BKHCN dated March 31, 2017, on amending and supplementing several articles of the Circular No. 28/2012/TT-BKHCN dated December 12, 2012;

Pursuant to the Decision No. 1186/QD-KT3 dated June 25, 2013, of the director of Technical Center 3 stipulating the content and procedures for certifying products that conform to national technical standards and regulations;

At the request of the head of the product certification department,

DECIDE:

Article 1: Granting Certificate No. 12-07 (KH1-CNL-2019) for the medical rubber gloves including non-sterile type I, powder or powder-free types conforming to ASTM D3578-05 standard (see details in the certificate), produced by VRG Khai Hoan Joint Stock Company.

Article 2: Certification is valid from May 4, 2019, to May 3, 2022.

Article 3: During the validity period of the certificate, the VRG Khai Hoan Joint Stock Company must strictly comply with the provisions on the rights and responsibilities of the certified establishment and the relevant provisions of the regulation QDKT3 28 - defining the content and procedures for certifying products conforming to national technical standards and regulations.

Recipient:

- As Article 4;
- Archived: VT, N7.

ON BEHALF OF DIRECTOR

DEPUTY DIRECTOR

(signed and sealed)

Mai Van Sung

PRODUCT'S CERTIFICATES

PROVINCIAL PEOPLE'S COMMITTEE
OF BA RIA- VUNG TAU

DEPARTMENT OF JUSTICE

No.: 728/STP-BTTP

On implementing urgent measures to prevent and combat the Covid-19 Pandemic

SOCIALIST REPUBLIC OF VIETNAM

Independence – Freedom – Happiness

Ba Ria- Vung Tau, April 1, 2020

Respectfully addressed to: Notarial practice organizations in Ba Ria- Vung Tau province.

On March 31, 2020, the Prime Minister of the Government issued the Instruction No. 16/CT-TTg on the implementation of measures to prevent and combat the Covid-19 Pandemic; People's Committee of Ba Ria – Vung Tau province issued the Official Missive No. 3146/UBND-VP dated March 31,2020 on deplopying a number of specific regulations and implementing preventive urgent measures to prevent and combat the Covid-19 pandemic in Ba Ria - Vung Tau province.

Strictly implementing the Instruction No. 16/CT-TTg dated March 31, 2020 of the Prime Minister and the Missive No. 3146/UBND-VP dated March 31, 2020, of the Provincial People's Committee with a spirit of considering health and human life important than everything; continuing to prevent combat the Covid-19 Pandemic, the Department of Justice informed notarial practice organizations in Ba Ria - Vung Tau province as follows:

1. Notarial practice organizations temporarily stop operating at within 15 days from 0:00 a.m on April 1, 2020.

2. Notary and staff members of notarial practice organizations strictly conduct social isolation and under the direction from the local to the central office.

Actively and steadily self-comply with requirements and measures to prevent and combat the pandemic, actively participate in the voluntary medical declaration, and implement measures to protect ourselves and our families; participate responsibly in the prevention and combat of the Covid-19 pandemic of the authorities and the community.

Director of the Department of Justice recommends that the notarial practice organizations in Ba Ria- Vung Tau province seriously implement./.

Recipient:

- As above;
- Provincial People's Committee;
- Deputy Director of the Department;
- Office of the Department;
- Archived: VT, BTTP.

DIRECTOR OF DEPARTMENT OF JUSTICE

(signed and sealed)

Ho Van Hung

PRODUCT'S CERTIFICATES

BINH DUONG DEPARTMENT OF HEALTH	**SOCIALIST REPUBLIC OF VIETNAM**
	Independence – Freedom – Happiness
No. 170000059/PCBA-BD	*Binh Duong, November 9, 2017*

WRITTEN RECEIPT

Application for announcement of standards applicable to type A medical equipment

1. Name of announcing institution: **VRG KHAI HOAN JOINT STOCK COMPANY**

2. Address: Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province

3. Suggested report no.: 01/KH-VRG dated November 9, 2017

4. Type A medical equipment:

Name of medical equipment: Nitrile examination gloves

Type/ product code: KHPPEX

Name of manufacturer: VRG Khai Hoan Joint Stock Company

Address of manufacturer: Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province

Applied standards: Type A

5. Information on owner of medical equipment:

Name of owner: VRG Khai Hoan Joint Stock Company

Address of owner: Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong

6. Information on the warranty facility:

7. Components of record

1	Written announcement of the applicable standards of medical equipment belonging to A	x
2	Certificate of quality management standards	x
3	Detailed appendices of medical equipment	x
4	Classification list of medical equipment	x
5	Receipt of application for announcement of eligibility for production of medical equipment or valid certificate of quality management standards at the time of submission of the application for announcement of imported medical equipment	x
6	Authorization letter of the owner of the medical equipment	x
7	Certificate of eligibility for warranty	x
8	Description of the technical summary of medical equipment	x
9	Certificate of conformity or certificate of standard applied by the owner of the medical equipment	x

PRODUCT'S CERTIFICATES

VTM VIETNAM JOINT STOCK COMPANY
No.: 289/170000035/PCBPL-BYT

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Hanoi, November 1, 2017

CLASSIFICATION OF MEDICAL EQUIPMENT

To: **VRG Khai Hoan Joint Stock Company**

Pursuant to the Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government on the management of medical equipment;

Pursuant to the Circular No. 39/2016/TT-BYT dated October 28, 2016 of the Ministry of Health on detailed regulations on classification of medical equipment;

Pursuant to the Circular No. 42/2016/TT-BYT dated November 15, 2016 of the Ministry of Health on regulations on recognition of classification of medical equipment;

Principles used for classification: Rule 4, Part II, Appendix I, Circular 36/2016/TT-BYT

We classify medical equipment as follows:

No.	Name of medical equipment	Species, code of products	Manufacturer, country of origin	Country of owner	Type of medical equipment
1	Powered latex examination gloves	KHPPEX	VRG Khai Hoan Joint Stock Company, Vietnam	VRG Khai Hoan Joint Stock Company, Vietnam	Type A
2	Powered-free latex examination gloves	KHPFEX	VRG Khai Hoan Joint Stock Company, Vietnam	VRG Khai Hoan Joint Stock Company, Vietnam	Type A
3	Non-sterile latex surgical gloves	KHPPSS	VRG Khai Hoan Joint Stock Company, Vietnam	VRG Khai Hoan Joint Stock Company, Vietnam	Type A
4	Sterile latex surgical gloves	KHPPSS	VRG Khai Hoan Joint Stock Company, Vietnam	VRG Khai Hoan Joint Stock Company, Vietnam	Type A

PRODUCT'S CERTIFICATES

BINH DUONG DEPARTMENT OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

No. 170000059/PCBA-BD

Binh Duong, November 7, 2017

WRITTEN RECEIPT
Announcement Record of eligibility to manufacture medical equipment

1. Name of announcing institution: **VRG KHAI HOAN JOINT STOCK COMPANY**

2. Address: Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province

(Name of Manufacturer: **VRG Khai Hoan Joint Stock Company, Address:** Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province)

3. Tel: +842743591220 Fax: ……..

4. Suggested report no.: 01/2017/KH-BD dated November 5, 2017

5. Name of medical equipment manufactured by announcing institution:

Powder examination gloves, Powder-free examination gloves, Non-sterile examination gloves, Sterile examination gloves, Nitrile examination gloves

6. Components of record

1	Written assignment, appointment of professional managers in charge of production facilities	x
2	Working time record	x
3	Documents and certificates of training in medical equipment technology or management of medical equipment by a person in charge of professional activities	x
4	Written announcement of eligibility for production	x
5	Human resource declaration	x
6	Written assignment, appointment of professional managers in charge of production facilities	x
7	A certificate of quality management standard conformity	x
8	Documents proving that the location, area and factory are suitable for the medical equipment of the manufacturer	x
9	Records of equipment and production processes, quality management consistent with the requirements of the type of medical equipment that the facility produces	x
10	Make contract with a facility capable of inspecting quality to meet the requirements of the manufactured medical equipment	
11	Records of equipment storage warehouse	x
12	Records of means transporting medical equipment	x

PRODUCT'S CERTIFICATES

VIETNAM'S MINISTRY OF HEALTH **SOCIALIST REPUBLIC OF VIETNAM**

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Hanoi, October 2, 2019

CERTIFICATE OF FREE SALES

1. Certificate No.: 43/CFS/BYT-TB-CT

2. Product(s): Nitrile examination gloves

3. Model: KHPFNT

4. Product(s) Owner: VRG Khai Hoan Joint Stock Company

Address: Land parcel No. 233, Map No. 37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Vietnam

5. Manufacturer: VRG Khai Hoan Joint Stock Company

- Address: Land parcel No. 233, Map No. 37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Vietnam

- Address of Head Office: Land parcel No. 233, Map No. 37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Vietnam

This is to certify that the above product(s) comply with the relevant standards of the S.R. Vietnam or equivalent and are allowed to be sold in Vietnam. The exportation of the product(s) is not restricted.

This certificate is valid for three years from the date of issuance.

FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL
DEVICE & CONSTRUCTION
DIRECTOR
(signed and sealed)
Nguyen Minh Tuan