VRG KHAI HOAN JSC

HỒ SƠ

Phân phối cung cấp

SẢN PHẨM

KHẨU TRANG
ĐỒ BẢO HỘ
GĂNG TAY Y TẾ

2020

MỌI THÔNG TIN XIN VUI LÒNG LIÊN HỆ ☎ Mr. Long 091.186.1119

VRG KHAI HOAN JSC

Đạt tiêu chuẩn ***ISO 9001:2015; ISO 13485:2016;***

Có chứng chỉ ***FDA 510K xuất hàng đi Mỹ,***

Tiêu chuẩn ***CE Marking*** xuất hàng đi ***Châu Âu,***

Chứng nhận của Bộ Y tế và Giấy chứng nhận ***QUATEST3***

GĂNG TAY KHẢI HOÀN

VGLOVE

CÁC DÒNG SẢN PHẨM

- GĂNG TAY NITRILE
  (Có bột/ không bột)
- GĂNG TAY LATEX
  (Có bột/ không bột)
- GĂNG TAY PHẪU THUẬT TIỆT TRÙNG

CE Marking

ISO SA8000

QUATEST3

ISO 9001:2015

Free Sale's Certificate

FDA 510K

Circulation Certificate

Mr. Long 091.186.1119

VRG KHAI HOAN JSC

GĂNG TAY CÓ BỘT

VGLOVE

THÔNG TIN SẢN PHẨM

Sản phẩm	**Găng tay cao su khám bệnh dạng có bột**		
Nguyên liệu	Mủ kem (latex) ly tâm tự nhiên		
Hàm lượng bột	≤10mg /dm^2		
Nồng độ Protein	Protein tách chiết trong nước: 200ug/g hoặc thấp hơn lượng công bố này		
Màu sắc	Màu cao su tự nhiên		
Đặc điểm	Dùng được cả hai tay, cổ tay được se viền, bề mặt găng tay trơn hoặc vùng bàn tay nhám		
Qui cách đóng gói	100cái / hộp, 10 hộp / thùng		
Nhãn hiệu	**VGLOVE**		
Kích thước	**Size**	**Chiều rộng lòng bàn tay (mm)**	**Chiều dài (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
Độ dày	**Vị trí đo**		**Một lớp (mm)**
	Đầu ngón tay(13 ± 3mm tại tâm điểm ngón tay)		min 0.01
	Lòng bàn tay (tại tâm điểm lòng bàn tay)		min 0.01
Đặc tính cơ học	**Trước lão hoá**		**Sau lão hoá**
	(70 ± 2oC trong 7 ngày)		
	Sức căng cơ (Mpa)	min 18.0	min 14.0
	Độ giãn (%)	min 650	min 500
Chức năng và Tác dụng	- Tránh tiếp xúc trực tiếp với các chất độc hại và nguy hiểm không mong muốn		
	- Dễ đeo và khó bị cuộn tròn khi đeo		

VRG KHAI HOAN JSC

GĂNG TAY CÓ BỘT

VGLOVE

HÌNH ẢNH SẢN PHẨM

FDA 510K

QUATEST3

Mặt sau

Mặt trên/dưới

Sản phẩm thực tế

Mặt trước

Mặt trái/phải

Mr. Long 091.186.1119

VRG KHAI HOAN JSC

GĂNG TAY KHÔNG BỘT

VGLOVE

THÔNG TIN SẢN PHẨM

Chất liệu	**Cao su Nitrile nhân tạo**
Loại	Không bột chưa tiệt trùng
	dùng cho cả hai tay; bề mặt đầu ngón tay nhám; xe viền cổ tay; Màu trắng hay có màu (Xanh dương, Xanh dương nhạt,...)
Tiêu chuẩn chất lượng	Phù hợp với các tiêu chuẩn ASTM D6319
	Sản xuất theo hệ thống quản lý chất lượng ISO 9001: 2008, ISO 13485:2003, ISO 22000:2005.
	Sản xuất từ 100% nitrile (Acrylonitrile-Butadiene)
Kích thước găng tay	Extra-small, Small, Medium, Large, Extra-large.
	Được đánh dấu Size trên thùng hàng bằng mực đen.
Bảo quản	Bảo quản ở nơi khô ráo mát mẻ, nhiệt độ không cao hơn 30°C.
Hạn sử dụng	3 năm kể từ ngày sản xuất

KÍCH THƯỚC	**TIÊU CHUẨN**	
	VRG KHAI HOAN	ASTM D6319
Chiều dài (mm)	230 min	220 min (XS, S)
		230 min (M, L, XL)
Chiều rộng (mm)	75 ± 5 (XS)	70 ± 10 (XS)
	85 ± 5 (S)	80 ± 10 (S)
	95 ± 5 (M)	95 ± 10 (M)
	105 ± 5 (L)	110 ± 10 (L)
	115 ± 5 (XL)	120 ± 10 (XL)
Độ dày (mm)	Ngón tay: 0. 08 mm min	Ngón tay : 0.05 mm min
	Lòng bàn tay: 0.06 mm min	Lòng bàn tay : 0.05 mm min

VRG KHAI HOAN JSC

GĂNG TAY KHÔNG BỘT

VGLOVE

THÔNG TIN SẢN PHẨM

CHỈ TIÊU LÝ HÓA

Tensile	Tensile strength (MPA) Trước lão hóa: 18Mpa min Sau lão hóa: 20Mpa min Elongation at break (%) Trước lão hóa: 600% min Sau lão hóa: 500% min	Tensile strength (MPA) Trước lão hóa: 14Mpa min Sau lão hóa: 14Mpa min Elongation at break (%) Trước lão hóa: 500% min Sau lão hóa: 400% min
Hàm lượng bột	Tối đa 2 mg / găng	
Hàm lượng protein	Không có Protein	

ISO 13485 Medical Devices Quality Management

HACCP & GMP Food Safety Management

ISO 22000 Food Safety System Certification

ISO 9001 Quality Management

Free Sale's Certificate

ISO 9001:2015

QUATEST3

FDA 510K

ISO SA8000

CE Marking

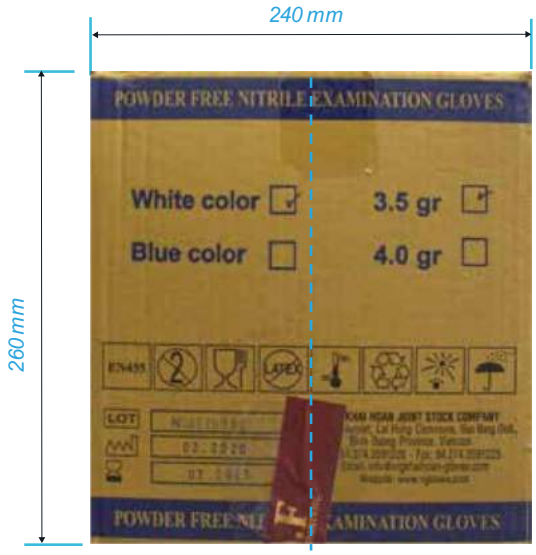
HÌNH ẢNH SẢN PHẨM

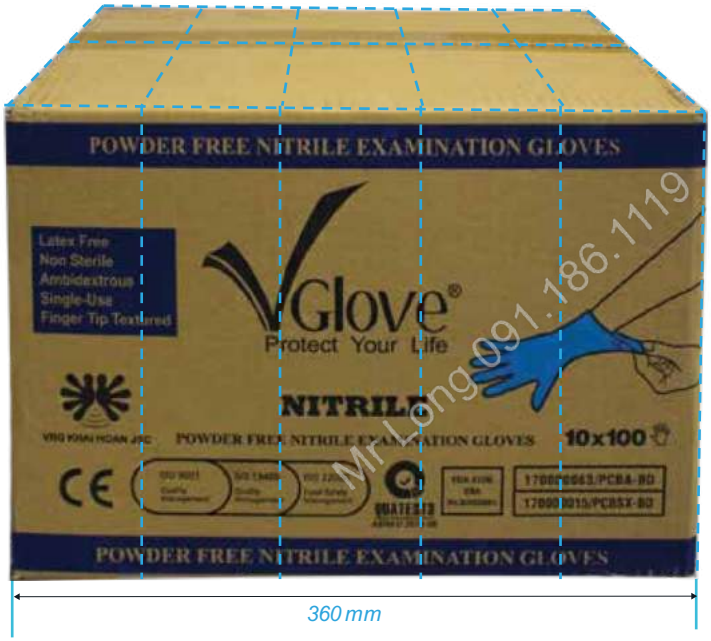
QUY CÁCH THÙNG CARTON

Kích thước: 360 mm x 260 mm x 240 mm

Trọng lượng: ~4kg/ Thùng

Số lượng 10 hộp / thùng





Mr. Long 091.186.1119

VRG KHAI HOAN JSC

GĂNG TAY KHÔNG BỘT

VGLOVE

HÌNH ẢNH SẢN PHẨM

Sản phẩm thực tế

Găng tay trắng

Găng tay xanh

Mặt trên/dưới

Mặt trước

Mặt sau

Mặt trái/phải

Mr. Long 091.186.1119

VRG KHAI HOAN JSC

GĂNG PHẪU THUẬT TIỆT TRÙNG

VGLOVE

THÔNG TIN SẢN PHẨM

Sản phẩm	**Găng tay cao su phẫu thuật tiệt trùng, tiệt trùng bằng khí E.O**		
Nguyên liệu	Mủ kem (latex) ly tâm tự nhiên		
Hàm lượng bột	≤10 mg/dm2		
Hàm lượng protein chiết xuất	≤200µg/găng tay		
Màu sắc	Màu cao su tự nhiên		
Đặc tính	Bàn tay hình cong, phân biệt tay trái, tay phải viền mép cuốn		
Quy cách đóng gói	1 đôi/bịch, 50 bịch/hộp, 4 hộp/thùng		
Nhãn hiệu	Vglove		
Kích thước	**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
Độ dày	0.10 mm		
Đặc tính cơ học		**Trước lão hóa**	**Sau lão hóa**
	Lực đứt tối thiểu (MPA)	21	16
	Độ giãn tối thiểu tại thời điểm đứt (%)	700	550
Trọng lượng (gam) Dung sai: ± 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

VRG KHAI HOAN JSC

GĂNG PHẪU THUẬT TIỆT TRÙNG

VGLOVE

THÔNG TIN SẢN PHẨM

Chức năng và tác dụng	- Găng tay phẫu thuật tiệt trùng được sử dụng trong quá trình khám, chuẩn đoán điều trị và phẫu thuật, nhằm bảo vệ tránh lây truyền bệnh giữa bệnh nhân và người sử dung găng tay phẫu thuật
	- Tính phân biệt tay trái, tay phải cộng thêm tính mềm mại của sản phẩm mang lại cảm giác thoải mái và vừa vặn cho người sử dụng. Ngoài ra, người sử dụng sẽ có cảm giác thoải mái hơn với chức năng giảm tiết mồ hôi tay gây cảm giác khó chịu
	- Bề mặt trơn láng tạo cảm giác tự nhiên, dễ chịu và thao tác dễ dàng hơn. Đồng thời cổ tay được se viền nên dễ đeo và tránh bị rách
	- Lượng bột trong mức cho phép – tác nhân gây ngứa và viêm da khi sử dụng
	- Mức protein và hoá chất trên găng thấp nhất nhằm hạn chế các dị ứng về da đối với người sử dụng
Tiêu chuẩn đánh giá	Dựa theo tiêu chuẩn đánh giá chất lượng sản phẩm của Mỹ - ASTM 3578 (05), AQL 1.5

QUY CÁCH THÙNG CARTON

Kích thước: 580 mm x 300 mm x 450 mm

Số lượng: **8** hộp / thùng

Trọng lượng: ~ 15kg/ thùng

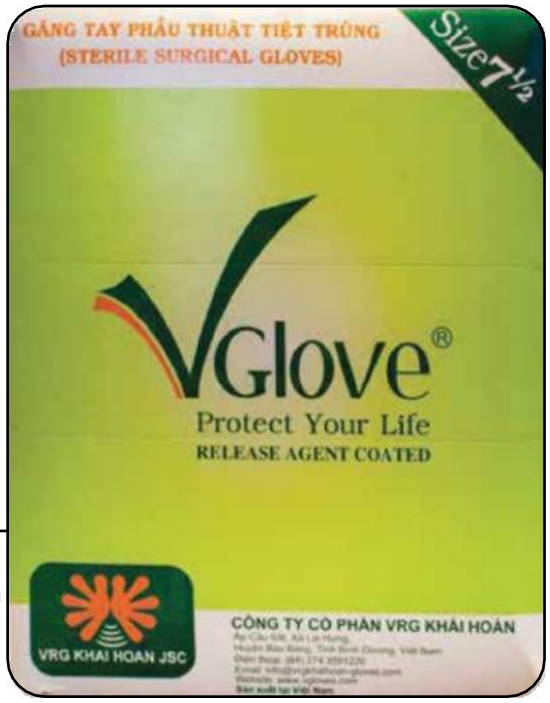
VRG KHAI HOAN JSC

GĂNG PHẪU THUẬT TIỆT TRÙNG

VGLOVE

HÌNH ẢNH SẢN PHẨM

Mặt trái



Mặt trước/sau

Mặt phải

Mặt trên/dưới

Sản phẩm thực tế

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By Royal Charter

Giấy Chứng Nhận

THỰC HÀNH SẢN XUẤT TỐT – GMP

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng, Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

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**

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1 / 1

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Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG - ISO 9001:2015

Xác nhận rằng:

CÔNG TY CỔ PHẦN VRG KHẢI HOÀN
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **FM 548618**

và thực hiện Hệ Thống Quản Lý Chất Lượng phù hợp với các yêu cầu của ISO 9001:2015 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: Chris Cheung, Phụ Trách Sự Tuân Thủ & Rủi Ro Châu Á Thái Bình Dương

Ngày đăng ký đầu tiên: **01/06/2009**
Ngày sửa đổi sau cùng: **30/05/2018**

Ngày hiệu lực: **01/06/2018**
Ngày hết hiệu lực: **31/05/2021**

Trang: 1/1

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Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG - ISO 13485:2016 & EN ISO 13485:2016

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **MD 548620**

và thực hiện Hệ Thống Quản Lý Chất Lượng phù hợp với các yêu cầu của ISO 13485:2016 & EN ISO 13485:2016 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: Stewart Brain, Giám Đốc Tuân Thủ & Rủi Ro – Thiết Bị Y Tế

Ngày đăng ký đầu tiên: **18/05/2009**
Ngày sửa đổi sau cùng: **02/05/2018**

Ngày hiệu lực: **18/05/2018**
Ngày hết hiệu lực: **17/05/2021**

Trang: 1/1

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Giấy Chứng Nhận

HỆ THỐNG TRÁCH NHIỆM XÃ HỘI - SA 8000:2014

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **SA 598117**

và thực hiện Hệ thống Trách Nhiệm Xã Hội phù hợp với các yêu cầu của Tiêu Chuẩn Trách Nhiệm Xã Hội SA 8000:2014 cho phạm vi:

Sản xuất và phân phối găng tay y tế cao su có bột và không bột, găng tay cao su nitrile bao gồm các quá trình tiếp nhận nguyên vật liệu latex/ nitrile, phối trộn, tạo đông, lưu hóa, tách chiết, nhúng bột bắp/chlorine, sấy khô, kiểm tra và đóng gói.

Các quá trình gia công ngoài: Không.
Các quá trình hợp đồng ngoài: Không.

Đại diện cho tập đoàn BSI: *Tổng Giám Đốc BSI Ấn Độ, Venkataram Arabolu*

Ngày đăng ký đầu tiên: **19/11/2013**
Ngày sửa đổi sau cùng: **11/11/2019**

Ngày hiệu lực: **19/11/2019**
Ngày hết hiệu lực: **18/11/2022**

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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

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

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

EmergoEurope.com

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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.

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 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

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

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.

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email: info@satra.com
www.satra.com

UKAS TESTING 0248

Customer details:	VRG Khai Hoan JSC Cau Sat Hamlet Lai Hung Commune Bau Bang District Binh Duong Province Vietnam	SATRA reference:	CHM0273594/1830/LH /A
		Your reference:	
		Date of report:	5th September 2018
		Samples received:	25th July 2018
For the attention of:	Hoa Hoang	Date(s) work carried out:	22nd to 24th August 2018

TECHNICAL REPORT

Subject: EN 16523-1: 2015 resistance to permeation by chemicals on gloves described as PFNBR

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%.

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

WORK REQUESTED:

Samples of gloves described as PFNBR were received by SATRA on the 25th July 2018 for testing in accordance with EN 16523-1:2015 and assessment in accordance with the requirements of EN ISO 374-1: 2016.

SAMPLES SUBMITTED:

Samples described as PFNBR

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of gloves described as PFNBR achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	4
37% Formaldehyde (CAS: 50-00-0)	6

Full results are reported in the following tables.

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

TESTING REQUIRED:

- EN 16523-1:2015 - Determination of material resistance to permeation by chemicals. Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016 - Protective gloves against dangerous chemicals and micro-organisms. Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual result achieved per chemical.

SATRA TECHNOLOGY

TECHNICAL REPORT

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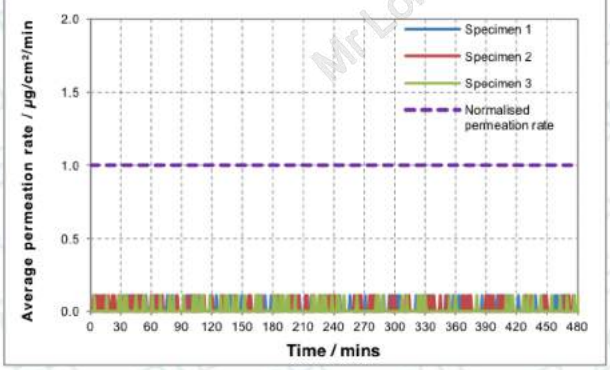
Test/Property	Sample reference:	PFNBR		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium Hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)	
	1	0.9	>480	
	2	0.09	>480	
	3	0.08	>480	
		Test result:	>480	
		UoM:	< 1	
Visual appearance of specimens after testing:		Slightly swollen		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium hydroxide



SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

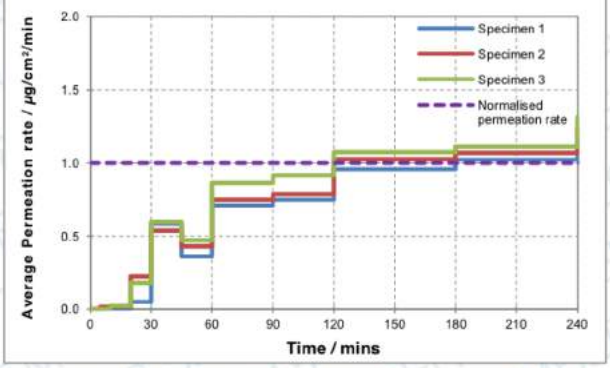
Test/Property	Sample reference:	PFNBR		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 40% Hydrogen peroxide		Level 4
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)▼	
	1	0.08	Between 181-240	
	2	0.08	Between 121-180	
	3	0.09	Between 121-180	
		Test result:	**Between 121-180**	
		UoM:	**See Below**	
Visual appearance of specimens after testing:		Swollen		

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

PERMEATION RATE GRAPHS

Challenge chemical: 30% Hydrogen peroxide



SATRA TECHNOLOGY

TECHNICAL REPORT

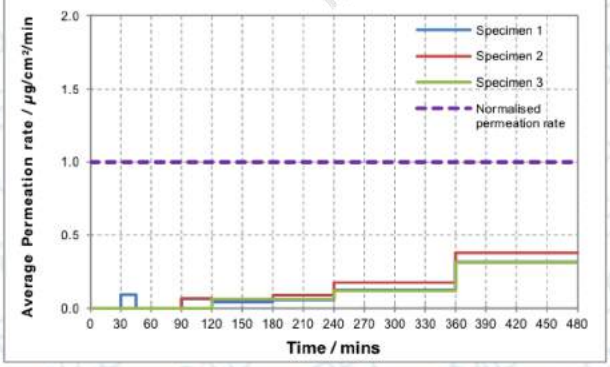
UKAS TESTING 0248

Test/Property	Sample reference:	PFNBR		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	1	0.09	>480	
	2	0.09	>480	
	3	0.10	>480	
		Test result:	**>480**	
		UoM:	**< 1**	
Visual appearance of specimens after testing:	Swollen and discoloured			

Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

PERMEATION RATE GRAPHS (FORMALDEHYDE)

Challenge chemical: 37% Formaldehyde



SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

⌂ EN 16523-1:2015 does not require the test specimen thicknesses to be reported, this information is indicative only.

▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015 is not possible.

SATRA TECHNOLOGY

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TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.

1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing.

1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

(a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
(b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
(c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
Fax +44 (0) 1536 410626
email: info@satra.co.uk
www.satra.co.uk

UKAS TESTING 0248

Customer details: VRG Khai Hoan Joint Stock Company
Cau Sat Hamlet
Lai Hung Commune
Ben Cat District
Binh Duong
Vietnam

For the attention of: Tra Trang

SATRA reference: SPC0225034 /1420/2

Your reference:

Date of report: 5 July 2014

Samples received: 16 May 2014

TECHNICAL REPORT

Subject: Testing of gloves described as "PFNBR" in accordance with EN 388: 2003, EN 420: 2003 + A1: 2009 & EN 374-2: 2003

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked † fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides for a confidence level of approximately 95%

Report signed by: D Harrison
Position: PPE Technologist
Department: Safety Products Centre

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING 0248

Work Requested

Samples of gloves, see Table 1 were received by SATRA, for testing in accordance with EN 388:2003, EN 420:2003 + A1:2009 and EN 374-2:2003.

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
PFNBR	7 - 10	White, Blue and Purple	Size: 10 Weight: 4.8g

PFNBR

Conclusion

Standard		Clause / Property	Result
EN 420:2003 + A1:2009	5.1	Length and fit	See Note A
	5.2	Dexterity	Level 5
EN 388:2003	6.1	Abrasion resistance	Level 0
	6.2	Blade cut resistance	Level 0
	6.3	Tear resistance	Level 0
	6.4	Puncture resistance	Level 0
EN 374-2:2003	4.1	Air Leak Test	Pass
	4.2	Water Leak Test	Pass

Signed: D Hartson

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Report signed by: D Harrison
Position: PPE Technologist
Department: Safety Products Centre

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 Glove is a non-colored, 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

TỔNG CỤC TIÊU CHUẨN
ĐO LƯỜNG CHẤT LƯỢNG
TRUNG TÂM KỸ THUẬT
TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3

Số: 0710/QĐ-KT3

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Tp. Hồ Chí Minh, ngày 04 tháng 5 năm 2019

QUYẾT ĐỊNH
Về việc cấp chứng nhận sản phẩm

GIÁM ĐỐC
TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3

Căn cứ Quyết định số 1668/QĐ-TĐC ngày 26/8/2014 của Tổng cục TCĐLCL về việc ban hành Điều lệ tổ chức và hoạt động của Trung tâm Kỹ thuật Tiêu chuẩn Đo lường Chất lượng 3 (Trung tâm Kỹ thuật 3);

Căn cứ Thông tư số 28/2012/TT-BKHCN ngày 12/12/2012 của Bộ Khoa học và Công nghệ quy định về công bố hợp chuẩn, công bố hợp quy và phương thức đánh giá sự phù hợp với tiêu chuẩn, quy chuẩn kỹ thuật và Thông tư số 02/2017/TT-BKHCN ngày 31/3/2017 về sửa đổi, bổ sung một số điều của Thông tư số 28/2012/TT-BKHCN ngày 12/12/2012;

Căn cứ Quyết định số 1186/QĐ-KT3 ngày 25/6/2013 của Giám đốc Trung tâm Kỹ thuật 3 quy định nội dung và thủ tục chứng nhận sản phẩm phù hợp tiêu chuẩn và quy chuẩn kỹ thuật quốc gia;

Theo đề nghị của Trưởng Phòng Chứng nhận sản phẩm,

QUYẾT ĐỊNH:

Điều 1. Cấp giấy chứng nhận số 12-07 (KH1-CNL-2019) cho sản phẩm găng tay cao su y tế, loại: không tiệt trùng loại I, có bột hoặc không có bột phù hợp tiêu chuẩn ASTM D 3578-05 (xem chi tiết tại giấy chứng nhận), do Công ty Cổ phần VRG Khải Hoàn sản xuất.

Điều 2. Giấy chứng nhận có hiệu lực từ ngày 04/5/2019 đến ngày 03/5/2022.

Điều 3. Trong thời gian hiệu lực của giấy chứng nhận, Công ty Cổ phần VRG Khải Hoàn phải thực hiện đúng các quy định về quyền và trách nhiệm của cơ sở được chứng nhận và các quy định liên quan trong quy định QĐKT3 28 - Quy định nội dung và thủ tục chứng nhận sản phẩm phù hợp tiêu chuẩn và quy chuẩn kỹ thuật quốc gia./.

Nơi nhận:
- Như điều 4;
- Lưu: VT, N7.

KT. GIÁM ĐỐC
PHÓ GIÁM ĐỐC

TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3

Mai Văn Sủng

ỦY BAN NHÂN DÂN
TỈNH BÀ RỊA - VŨNG TÀU
SỞ TƯ PHÁP

Số: 728 /STP-BTTP
V/v thực hiện các biện pháp cấp bách phòng, chống dịch Covid-19.

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Bà Rịa - Vũng Tàu, ngày 01 tháng 4 năm 2020

Kính gửi: Các tổ chức hành nghề công chứng
trên địa bàn tỉnh Bà Rịa - Vũng Tàu.

Ngày 31/3/2020, Thủ tướng Chính phủ đã ban hành Chỉ thị số 16/CT-TTg về việc thực hiện các biện pháp cấp bách phòng, chống dịch Covid-19; Ủy ban nhân dân tỉnh Bà Rịa - Vũng Tàu đã có Công văn số 3146/UBND-VP ngày 31/3/2020 về triển khai một số chế độ đặc thù và thực hiện các biện pháp cấp bách phòng, chống dịch Covid-19 trên địa bàn tỉnh Bà Rịa - Vũng Tàu.

Thực hiện nghiêm Chỉ thị số 16/CT-TTg ngày 31/3/2020 của Thủ tướng Chính phủ và Công văn số 3146/UBND-VP ngày 31/3/2020 của Ủy ban nhân dân tỉnh với tinh thần coi trọng sức khỏe và tính mạng của con người là trên hết, tiếp tục chủ động ngăn chặn, kiểm soát dịch bệnh Covid-19, Sở Tư pháp thông báo tới các tổ chức hành nghề công chứng trên địa bàn tỉnh Bà Rịa - Vũng Tàu như sau:

1. Tạm ngưng hoạt động tại các tổ chức hành nghề công chứng trong vòng 15 ngày kể từ 0 giờ ngày 01 tháng 4 năm 2020.

2. Công chứng viên, các nhân viên thuộc các tổ chức hành nghề công chứng thực hiện nghiêm cách ly toàn xã hội theo chỉ đạo từ Trung ương đến địa phương.

Chủ động, cùng nhân dân tự giác chấp hành các yêu cầu, các biện pháp phòng chống dịch, tích cực tham gia khai báo y tế tự nguyện, thực hiện đầy đủ các biện pháp tự bảo vệ mình, gia đình mình; tham gia có trách nhiệm với các hoạt động phòng, chống dịch Covid-19 của các cơ quan chức năng và cộng đồng.

Giám đốc Sở Tư pháp đề nghị Trưởng các tổ chức hành nghề công chứng trên địa bàn tỉnh Bà Rịa - Vũng Tàu nghiêm túc thực hiện./.

Nơi nhận:
- Như trên;
- UBND tỉnh (b/c);
- Các PGĐ Sở;
- Văn phòng Sở;
- Lưu: VT, BTTP.

GIÁM ĐỐC

SỞ TƯ PHÁP

Hồ Văn Hùng

Ở Y TẾ BÌNH DƯƠNG

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM

Độc lập - Tự do - Hạnh phúc

Số :170000063/PCBA-BD

Bình Dương, ngày 09 tháng 11 năm 2017

PHIẾU TIẾP NHẬN

Hồ sơ công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại A

1. Tên cơ sở công bố: CÔNG TY CỔ PHẦN VRG KHẢI HOÀN
2. Địa chỉ: Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương
3. Số văn bản đề nghị của cơ sở : 05/KH-VRG Ngày: 09/11/2017
4. Trang thiết bị y tế thuộc loại A

Tên trang thiết bị y tế: Găng tay khám bệnh có bột (loại cao su)

Chủng loại/mã sản phẩm: KHPPEX

Tên cơ sở sản xuất: Công ty Cổ phần VRG Khải Hoàn

Địa chỉ cơ sở sản xuất: ấp Cầu Sắt, Xã Lai Hưng, huyện Bàu Bàng, tỉnh Bình Dương

Tiêu chuẩn áp dụng: loại A

5. Thông tin về chủ sở hữu trang thiết bị y tế :

Tên chủ sở hữu: Công ty Cổ phần VRG Khải Hoàn

Địa chỉ chủ sở hữu: ấp Cầu Sắt, Xã Lai Hưng, huyện Bàu Bàng, tỉnh Bình Dương

6. Thông tin về cơ sở bảo hành:

7. Thành phần hồ sơ:

1	Văn bản công bố tiêu chuẩn áp dụng của trang thiết bị y tế thuộc loại A	x
2	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng	x
3	Phụ lục chi tiết trang thiết bị y tế	x
4	Bản phân loại trang thiết bị y tế	x
5	Phiếu tiếp nhận hồ sơ công bố đủ điều kiện sản xuất trang thiết bị y tế hoặc Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng còn hiệu lực tại thời điểm nộp hồ sơ công bố đối với trang thiết bị y tế nhập khẩu.	x
6	Giấy ủy quyền của chủ sở hữu trang thiết bị y tế	x
7	Giấy xác nhận đủ điều kiện bảo hành	x
8	Tài liệu mô tả tóm tắt kỹ thuật TTBYT	x
9	Giấy chứng nhận hợp chuẩn hoặc Bản tiêu chuẩn mà chủ sở hữu trang thiết bị y tế công bố áp dụng	x

CÔNG TY CỔ PHẦN VTM VIỆT NAM

Số: 289..../ 170000035/ PCBPL-BYT

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Hà Nội, ngày 01 tháng 11 năm 2017

BẢN PHÂN LOẠI TRANG THIẾT BỊ Y TẾ

Kính gửi: **Công ty Cổ phần VRG Khải Hoàn**

Căn cứ Nghị định số: 36/2016/NĐ-CP ngày 15 tháng 5 năm 2016 của Chính phủ về quản lý trang thiết bị y tế;

Căn cứ thông tư số: 39/2016/TT-BYT ngày 28/10/2016 của Bộ Y tế về Quy định chi tiết việc phân loại trang thiết bị y tế;

Căn cứ thông tư số: 42/2016/TT-BYT ngày 15/11/2016 của Bộ Y tế về Quy định việc thừa nhận kết quả phân loại trang thiết bị y tế;

Nguyên tắc được sử dụng để phân loại: Quy tắc 4, Phần II, Phụ lục I, Thông tư 39/2016/TT-BYT.

Chúng tôi phân loại trang thiết bị y tế như sau:

TT	Tên trang thiết bị y tế	Chủng loại/ mã sản phẩm	Hãng, nước sản xuất	Hãng, nước chủ sở hữu	Loại trang thiết bị y tế
1	Găng tay khám bệnh có bột (loại cao su)	KHPPEX	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Loại A
2	Găng tay khám bệnh không bột (loại cao su)	KHPFEX	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Loại A
3	Găng tay phẫu thuật chưa tiệt trùng (loại cao su)	KHPPSS	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Loại A
4	Găng tay phẫu thuật tiệt trùng (loại cao su)	KHPPSS	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Công ty Cổ phần VRG Khải Hoàn, Việt Nam	Loại A

Y TẾ BÌNH DƯƠNG

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Số :170000015/PCBSX-BD

Bình Dương, ngày 07 tháng 11 năm 2017

PHIẾU TIẾP NHẬN
Hồ sơ công bố đủ điều kiện sản xuất trang thiết bị y tế

1. Tên cơ sơ công bố: CÔNG TY CỔ PHẦN VRG KHẢI HOÀN

2. Địa chỉ: Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương

(Sản xuất tại: Công ty Cổ phần VRG Khải Hoàn; Địa chỉ: ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương)

3. Điện thoại: +842743591220 Fax: .....

4. Số văn bản đề nghị của cơ sở: 01/2017/KH-BD Ngày : 05/11/2017

5. Tên trang thiết bị y tế cơ sở công bố sản xuất:
Găng tay khám bệnh có bột (loại cao su), Găng tay khám bệnh không bột (loại cao su), Găng tay phẫu thuật chưa tiệt trùng (loại cao su), Găng tay phẫu thuật tiệt trùng (loại cao su), Găng tay khám bệnh (loại Nitrile)

6. Thành phần hồ sơ:

1	Văn bản phân công, bổ nhiệm người phụ trách chuyên môn của cơ sở sản xuất	x
2	Bản xác nhận thời gian công tác	x
3	Văn bằng, chứng chỉ đào tạo về kỹ thuật thiết bị y tế hoặc quản lý thiết bị y tế của người phụ trách chuyên môn	x
4	Văn bản công bố đủ điều kiện sản xuất	x
5	Bản kê khai nhân sự	x
6	Văn bản phân công, bổ nhiệm người phụ trách chuyên môn của cơ sở sản xuất	x
7	Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng	x
8	Hồ sơ chứng minh địa điểm, diện tích, nhà xưởng sản xuất phù hợp với yêu cầu của loại trang thiết bị y tế mà cơ sở sản xuất	x
9	Hồ sơ về thiết bị và quy trình sản xuất, kiểm tra chất lượng phù hợp với yêu cầu của loại trang thiết bị y tế mà cơ sở sản xuất	x
10	Hợp đồng với cơ sở đủ năng lực kiểm tra chất lượng để kiểm tra chất lượng trang thiết bị y tế mà cơ sở sản xuất	x
11	Hồ sơ về kho tàng bảo quản trang thiết bị y tế	x
12	Hồ sơ về phương tiện vận chuyển trang thiết bị y tế	x

BỘ Y TẾ VIỆT NAM
VIET NAM MINISTRY OF HEALTH

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc
SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness
Hà nội, ngày 02 tháng 10 năm 2019

GIẤY CHỨNG NHẬN LƯU HÀNH TỰ DO
CERTIFICATE OF FREE SALES

1. Giấy chứng nhận số: 43 **/CFS/BYT-TB-CT**
- Certificate No:
2. Sản phẩm: Găng tay khám bệnh.
- Product(s): Nitrile examination gloves
3. Chủng loại/Model: KHPFNT
4. Công ty sở hữu hợp pháp: Công ty Cổ phần VRG Khải Hoàn.
- Product(s) Owner: VRG Khai Hoan Joint Stock Company.
- Địa chỉ: Thửa đất số 233, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương, Việt Nam.
- Address of Head Office: Land parcel No.233, Map No.37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Viet Nam.
5. Công ty sản xuất: Công ty Cổ phần VRG Khải Hoàn.
- Manufacturer: VRG Khai Hoan Joint Stock Company.
- Địa chỉ: Thửa đất số 233, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương, Việt Nam.
- Address of Head Office: Land parcel No.233, Map No.37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Viet Nam.

Văn bản này là để xác nhận rằng các sản phẩm trên tuân theo các tiêu chuẩn liên quan của Việt Nam hoặc tương đương và được phép bán tại Việt Nam. Việc xuất khẩu sản phẩm không bị hạn chế.

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.

Giấy chứng nhận này có hiệu lực 03 năm kể từ ngày ký.
This certificate is valid for three years from the date of issuance.

TL. BỘ TRƯỞNG
VỤ TRƯỞNG
VỤ TRANG THIẾT BỊ VÀ CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL DEVICE & CONSTRUCTION
DIRECTOR

Nguyễn Minh Tuấn

Designation: D7329 – 07 (Reapproved 2018)

Standard Specification for Food Preparation and Food Handling (Food Service) Gloves[1]

This standard is issued under the fixed designation D7329; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the properties necessary for thin film, unlined polymer gloves to be used in food preparation and food handling.

1.2 This specification is intended to serve as a referee and a guide to permit obtaining gloves of a consistent performance. The safe and proper use of gloves is excluded from the scope of this specification.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D882 Test Method for Tensile Properties of Thin Plastic Sheeting

D3578 Specification for Rubber Examination Gloves

D3767 Practice for Rubber—Measurement of Dimensions

D4679 Specification for Rubber General Purpose, Household or Beautician Gloves

D5151 Test Method for Detection of Holes in Medical Gloves

D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application

D5712 Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

D7246 Test Method for Detection of Holes in Polyethylene Food Service Gloves

2.2 *ISO Standard:*

ISO 2859-1 Sampling Procedures and Tables for Inspection by Attributes[3]

2.3 *Code of Federal Regulations—Title 21—Food and Drugs:*

21 CFR Parts 170–199[4]

3. Materials and Manufacture

3.1 Any material or composition that permits the glove to meet the specification identified by this standard and comply with the requirements of this specification and the regulations promulgated by the U.S. Food and Drug Administration concerning the materials used and permitted for direct food contact and the regulations concerning any powder or lubricants added to the gloves are acceptable.

4. Performance Requirements

4.1 Gloves shall be sampled in accordance with the AQL specified in Table 1 using a sampling plan derived from ISO 2859-1 or its equivalent, or other suitable statistical rationale.

4.2 Gloves shall be tested for freedom of holes as described in 5.1 and comply with the requirements of Table 1 for freedom from holes.

[1] This specification is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved July 1, 2018. Published August 2018. Originally approved in 2007. Last previous edition approved in 2012 as D7329 – 07 (2012). DOI: 10.1520/D7329-07R18.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.

TABLE 1 Performance Requirements

Characteristic	Related Defect	Inspection Level	AQL
Freedom from holes	holes	G-1	2.5
Dimensions	width, length, and thickness	S-2	4.0
Physical properties	before aging, after accelerated aging	S-2	4.0
Powder-free residue	exceeds max limit	N=5	N/A
Powder amount	exceeds recommended max limit	N=2	N/A
Protein content (natural rubber)	exceeds recommended max limit	N=3	N/A
Antigenic protein content (natural rubber)	exceeds recommended max limit	N=1	N/A

4.3 Gloves shall meet and be tested for dimensions and tolerances as described in 5.2 and comply with the performance requirements listed in Table 1 for dimensions.

4.4 Gloves shall meet and be tested for physical properties as described in 5.3 and comply with the performance requirements listed in Table 1 for physical properties.

4.5 Powder-free gloves shall be tested for glove powder residue per 5.4 and comply with 21 CFR Parts 170–199 (as applicable).

4.6 Powdered gloves shall be tested for glove powder amounts per 5.4 and comply with 21 CFR Parts 170–199 (as applicable).

4.7 *Protein:*

4.7.1 Gloves made from natural rubber shall be tested for compliance to the recommended aqueous soluble protein content limit as described in 5.6, or

4.7.2 Tested for compliance to the recommended antigenic protein content limit as described in 5.7.

5. Referee Test Methods

5.1 *Holes*—Gloves shall be tested in accordance with Test Method D5151 to an AQL of 2.5 as specified in Table 1 or as required by each existing material specific ASTM glove standard.

5.1.1 Polyethylene gloves shall be tested using Test Method D7246 to an AQL of 2.5 as specified in Table 1.

5.1.2 If food service gloves are made of a material type not described or specified in an existing ASTM glove standard and the material is a non-elastomer, then Test Method D7246 shall be used for the detection of holes to an AQL of 2.5 as specified in Table 1.

5.2 *Dimensions*—Gloves shall be tested for dimensions and tolerances in accordance with their individual standards or Practice D3767 to an AQL of 4.0 per Table 1 and as specified in Table 2a through Table 2f. Measurement locations are specified in Fig. 1.

5.2.1 Dimensions shall be expressed in millimetres (mm).

5.2.2 Values shall meet the requirements established in Table 3.

5.2.3 When the customer specifies thickness, it shall be measured using an appropriate instrument to measure thickness in accordance with Test Methods D412 and Practice D3767 in the location specified in Fig. 1.

5.3 *Physical Properties*—Gloves shall be tested for physical properties as described Test Methods D412 and to an AQL 4.0 per Table 1 and as specified in Table 3a through Table 3h. Accelerated aging shall be conducted in accordance with Test Method D573. Accelerated aging shall be conducted at 70 ± 2°C for a period of 168 ± 2 h on gloves that are no more than 12 months old from the date of manufacture.

5.3.1 Polyethylene gloves shall be tested for "Maximum Force at Yield" per Test Method D882 using die type "D".

5.4 *Powder (Powder-free Gloves)*—Gloves shall be tested for residual powders in accordance with Test Method D6124. Food Service gloves labeled as "Powder-free" shall adhere to the powder residue limit established in Specification D3578. All glove powders shall comply with 21 CFR Parts 170–199, as applicable. A powder, release agent, or lubricant not listed within 21 CFR Parts 170–199 shall not be used for gloves designed to contact food products.

5.5 *Powder (Powdered Gloves)*—Gloves shall be tested for maximum powder limit using Test Method D6124. Powdered Food Service gloves shall adhere to the maximum powder limit established in Specification D3578. All glove powders shall comply with 21 CFR Parts 170–199, as applicable. A powder, release agent, or lubricant not listed within 21 CFR Parts 170–199 shall not be used for gloves designed to contact food products.

5.6 *Aqueous Extractable Protein Content*—For gloves made from natural rubber, determine the aqueous extractable protein for each glove sample tested using Test Method D5712. Representative glove samples shall have a recommended aqueous soluble protein content limit (measured in $\mu g/dm^2$) in accordance with Specification D3578. Alternatively, representative glove samples may have a recommended antigenic protein content limit in accordance with Specification D3578.

5.7 *Antigenic Protein Content*—For gloves made from natural rubber determine the extractable antigenic protein for each glove sample tested using Test Method D6499. Representative glove samples shall have a recommended antigenic protein content limit (measured in $\mu g/dm^2$) in accordance with Specification D3578. Alternatively, representative glove samples may have a recommended aqueous soluble protein content limit in accordance with Specification D3578.

5.8 *Design*—Any glove design meeting the requirements of this standard and suitable for direct food contact may be used.

6. Quality Assurance

6.1 *Responsibility for Inspection*—When specified in the contract or purchase order, the supplier is responsible for performance of all inspection requirements.

6.2 Gloves shall be considered to meet the referee performance requirements when the test results meet the performance requirements found in Table 1.

6.3 Retests are permissible under the provisions of ISO 2859 with a documented statistical rationale.

7. Product Marking

7.1 *Glove Identification*—Each consumer package of gloves shall at a minimum be legibly marked with the following information: size, the name and trademark (if applicable) of the

TABLE 2 Dimensions and Tolerances

NOTE 1—Sizing that falls within the tolerance overlaps between two sizes may be labeled as a size range including both sizes, for example, small/medium and medium/large.

Table 2a Dimensions and Tolerances: Natural Rubber (Latex)

Designation	Size								Tolerance, mm
Width by size	6 75	6½ 83	7 89	7½ 95	8 102	8½ 108	9 114		±6
Width by	x-small 70	small 80	Unisize 85	medium 95		large 110	X-large 120	XX-large 130	±10
Length	220	220	220	230		230	230	230	Min
Thickness, mm				For All Sizes					
Finger				0.08					Min
Palm				0.08					Min
Cuff				0.08					Min

Table 2b Dimensions and Tolerances: Synthetic Rubber; Polychloroprene and Nitrile

Designation	Size								Tolerance, mm
Width by size	6 75	6½ 83	7 89	7½ 95	8 102	8½ 108	9 114		±6
Width by	x-small 70	small 80	Unisize 85	medium 95		large 110	X-large 120	XX-large 130	±10
Length	220	220	230	230		230	230	230	Min
Thickness, mm				For All Sizes					
Finger				0.05					Min
Palm				0.05					Min
Cuff				0.05					Min

Table 2c Dimensions and Tolerances: Vinyl (PVC)

Designation	Size								Tolerance, mm
Width by size	6 75	6½ 83	7 89	7½ 95	8 102	8½ 108	9 114		±6
Width by	x-small 70	small 80	Unisize 85	medium 95		large 110	X-large 120	XX-large 130	±10
Length	230	230	230	230		230	230	230	Min
Thickness, mm				For All Sizes					
Finger				0.05					Min
Palm				0.08					Min
Cuff				0.05					Min

Table 2d Dimensions and Tolerances: Low Density Polyethylene (LDPE)

Designation	Size					Tolerance, mm
Width by Range (mm)	x-small 95-135	small 100-140	medium 105-155	large 110-165	X-large 120-170	
Length (mm)	250	250	260	265	265	Min
Thickness, mm			For All Sizes			
Finger			0.018			Min
Palm			0.018			Min
Cuff			0.018			Min

Table 2e Dimensions and Tolerances: High Density Polyethylene (HDPE)

Designation	Size					Tolerance, mm
Width by Range (mm)	x-small 125-160	small 135-170	medium 145-180	large 155-190	X-large 165-200	
Length (mm)	210	210	210	210	210	Min
Thickness, mm			For All Sizes			
Finger			0.016			Min
Palm			0.016			Min
Cuff			0.016			Min

Table 2f Dimensions and Tolerances: Cast Polyethylene (CPE)

Designation	Size					Tolerance, mm
Width by Range (mm)	x-small 100-135	small 100-145	medium 115-155	large 130-165	X-large 135-170	
Length (mm)	285	285	300	300	300	Min
Thickness, mm			For All Sizes			

Finger	0.024	Min
Palm	0.024	Min
Cuff	0.024	Min

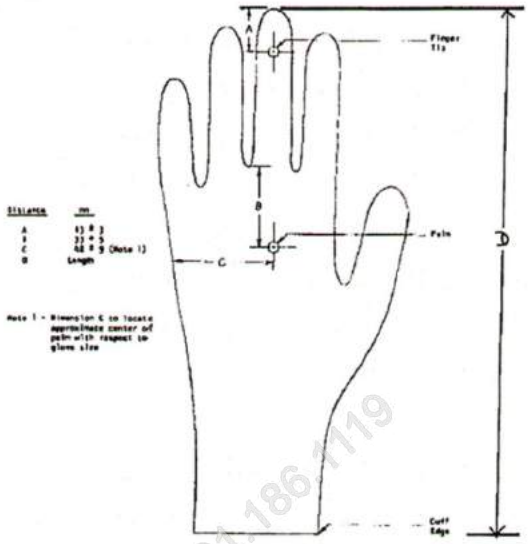

FIG. 1 Glove Measurement Locations

TABLE 3 Physical Requirements

Before Aging		After Accelerated Aging	
Table 3a Physical Requirements for Natural Rubber (Type I)			
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
18 MPa min	650 % min	14 MPa min	500 % min
Table 3b Physical Requirements for Natural Rubber (Type II)			
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
14 MPa min	650 % min	14 MPa min	500 % min
Table 3c Physical Requirements for Synthetic Rubber: Polychloroprene			
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
14 MPa min	500 % min	14 MPa min	400 % min
Table 3d Physical Requirements for Synthetic Rubber: Nitrile			
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
14 MPa min	500 % min	14 MPa min	400 % min
Table 3e Physical Requirements for Vinyl (PVC)			
Tensile Strength	Ultimate Elongation	Tensile Strength	Ultimate Elongation
9 MPa min	300 % min	9 MPa min	300 % min
Table 3f Physical Requirements for Low Density Polyethylene (LDPE)			
Max Force at Yield	Ultimate Elongation	Max Force at Yield	Ultimate Elongation
280 N/m min	500 % min	280 N/m min	500 % min
Table 3g Physical Requirements for High Density Polyethylene (HDPE)			
Max Force at Yield	Ultimate Elongation	Max Force at Yield	Ultimate Elongation
320 N/m min	500 % min	320 N/m min	500 % min
Table 3h Physical Requirements for Cast Polyethylene (CPE)			
Max Force at Yield	Ultimate Elongation	Max Force at Yield	Ultimate Elongation
360 N/m min	300 % min	360 N/m min	300 % min

manufacturer or supplier, the manufacturer's lot number, manufacturer's or supplier's contact information, and the country of origin.

8. Packaging and Storage

8.1 The gloves shall be packaged in a manner sufficient to protect them against excessive degradation. All packaging materials in direct contact with product surfaces shall be approved for food contact, and protect products from damage during transportation and storage.

8.2 No packaging material in contact with gloves is to contain substances that will impair the quality or use of the gloves.

8.3 All labeling for gloves compliant with this standard and scheduled to be sold in the United States shall comply with applicable U.S. government regulations.

8.4 Appropriate labeling for Food Service gloves shall include instructions for use or such instructions for use shall be made available to the purchaser or end-user that identify materials with which contact should be avoided because the identified material may degrade the gloves in use, compromise the barrier, or are otherwise harmful to the glove material. Limitations of the materials affecting the use of the glove shall be provided in the labeling or be made available to the purchaser or end user.

8.5 Appropriate environmental protection labeling requirements that affect the integrity of Food Service gloves shall be included on the packaging. Such labeling for Food Service gloves shall at a minimum include instructions or limitations that address the following: appropriate protection from exposure to light and excessive heat, environmental conditions that may compromise the food service glove material, and the appropriate storage temperatures or conditions, or both, for food service gloves. Such labeling shall be consistent with the applicable standard for the material.

8.6 Gloves compliant with this standard may be labeled with a statement that the gloves comply with this specification.

9. Keywords

9.1 food contact; gloves; natural rubber; polyethylene; synthetic rubber; vinyl

Test Report No. 7191212955-EEC19/03-WBH_CR2
(re-issue dated: 21 Jun 2019)
dated 14 Jun 2019

PSB Singapore

Add value.
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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Glove testing for freedom from hole.

TESTED FOR:

VRG Khai Hoan Join Stock Company
Cau Sat Hamlet
Lai Hung Commune
Bau Bang Dist
Binh Duong Province
Vietnam

SAMPLE SUBMISSION DATE:

07 Jun 2019

TEST DATE:

11 Jun 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Lot No.	Sample received	Manufacturer
1	Nitrile Gloves	-	6 boxes (100 pieces per box)	VRG Khai Hoan Join Stock Company

Lot size as specified by client: 150,001 to 500,000 pieces

Amendments:
The following amendments were made on 19 Jun 2019 and 21 Jun 2019:
The "Product Description" and "Manufacturer" under "DESCRIPTION OF SAMPLES" were amended as requested by client.
The "Client" under "TESTED FOR" was amended as requested by client.

TÜV SÜD PSB

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Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

Test Report No. 7191212955-EEC19/03-WBH_CR2
(re-issue dated: 21 Jun 2019)
dated 14 Jun 2019

PSB Singapore

METHOD OF TEST:

As requested by client, the test was conducted as follows:

EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from hole

RESULTS:

Sample: Nitrile Gloves

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	1	Passed

REMARKS:

1. The manufacturing batch code was not provided by the client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

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2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

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PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Glove testing for freedom from hole.

TESTED FOR:

VRG Khai Hoan Join Stock Company
Cau Sat Hamlet
Lai Hung Commune
Bau Bang Dist
Binh Duong Province
Vietnam

SAMPLE SUBMISSION DATE:

07 Jun 2019

TEST DATE:

12 Jun 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Sample received	Manufacturer
1	Latex Powder Free Gloves	Natural	-	6 boxes (100 pieces per box)	VRG Khai Hoan Join Stock Company

Lot size as specified by client: 150,001 to 500,000 pieces

Amendments:
The following amendments were made on 19 Jun 2019 and 21 Jun 2019:
The "Product Description" and "Manufacturer" under "DESCRIPTION OF SAMPLES" were amended as requested by client.
The "Client" under "TESTED FOR" was amended as requested by client.

TÜV SÜD PSB

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Part 1: Requirements and testing for freedom from hole

RESULTS:

Sample: Latex Powder Free Gloves

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	3	Passed

REMARKS:

1. The manufacturing batch code was not provided by the client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

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SUBJECT:

Glove testing for freedom from hole.

TESTED FOR:

VRG Khai Hoan Join Stock Company
Cau Sat Hamlet
Lai Hung Commune
Bau Bang Dist
Binh Duong Province
Vietnam

SAMPLE SUBMISSION DATE:

07 Jun 2019

TEST DATE:

11 Jun 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Sample received	Manufacturer
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RESULTS:

Sample: Latex Powder Gloves

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	8	Passed

REMARKS:

1. The manufacturing batch code was not provided by the client.

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