# NITRILE GLOVES

Medical Examination Gloves

- ✓ The safe and practical choice for every task
- Cuddle your hands protect to your health





Gloves are the important tool in preventing HAIs (Healthcare-associated Infection)
& cross-containmination.

Nitrile gloves made from Nitrile Butadiene Rubber (NBR).

That made gloves are widely used due to their **excellent protection**.







The excellent range includes:



**Excellent Protect** 



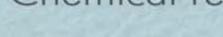
Thicker and stronger gloves



Elasticity with 3000 PSI

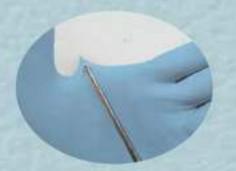


Chemical resistance



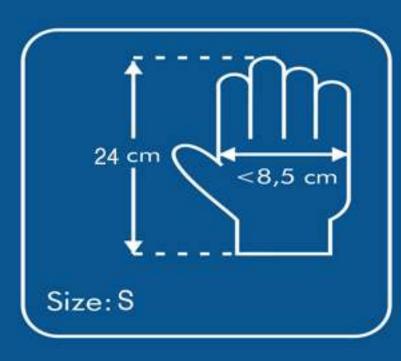


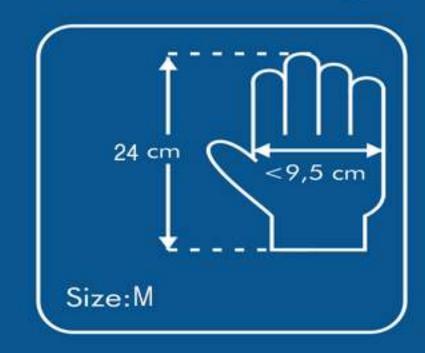


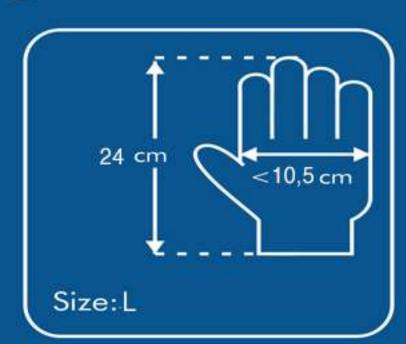




# How to choose the right gloves?



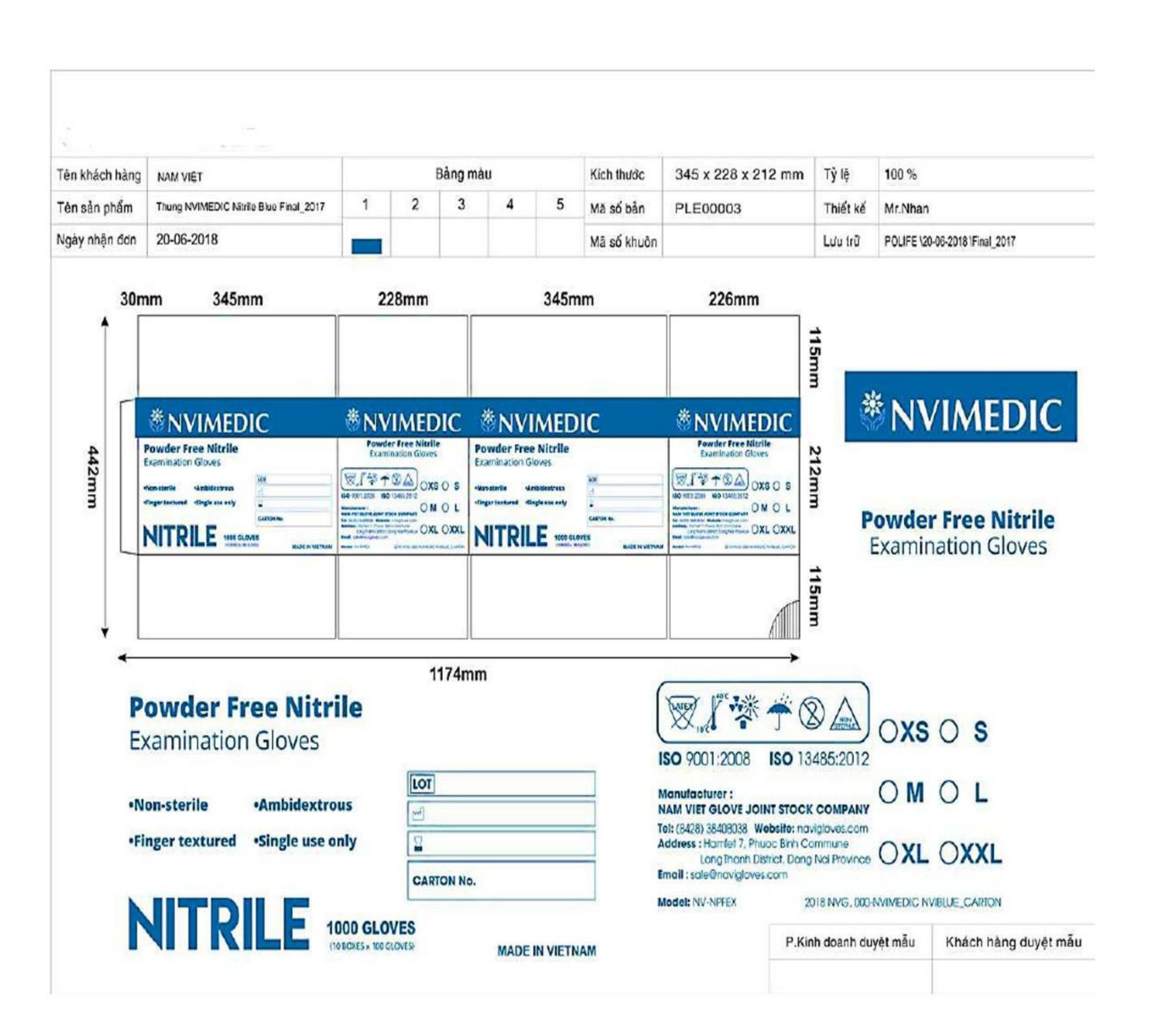




#### INFOMATION

Name	Nam Viet Nitrile Gloves	Package	100pcs/box
Туре	Medical Examination Gloves	Weight	400 gram to 650 gram
Size	S/M/L/XL	Carton	10 boxes/Carton
Material	Nitrile Butadiene Rubber (NBR)	Gross Weight	4,5Kg
Color	White/Blue	20ft Container	1700 Cartons
Origin	Vietnam	40ft Container	3000 Cartons

# Agreed Technical Data & Specification of Gloves Manufacturer NAM VIET GLOVES JOINT DTOCK COMPANT To be stamped by Seller



# Exhibit B:

Box design:

1 HỘP 100 CÁI – 10 HỘP/THÙNG



#### DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration 10903 New Hampshire Avenue Document Control Center - WO66-G609 Silver Spring, MD 20993-0002

November 7, 2016

Nam Viet Glove Joint Stock Company Ooi Loon Seng QA Manager Hamlet 7, Phuoc Binh Commune Long Thanh District Ho Chi Minh Dong Nai Province, VN 815300

Re: K162113

Trade/Device Name: Powder Free Nitrile Examination Gloves (Blue)

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: Class I Product Code: LZA

Dated: September 26, 2016 Received: October 3, 2016

#### Dear Ooi Loon Seng:

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 <u>Federal Register</u>.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

# DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

### Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

K162113.	93	
Device Name Powder Free Nitrile Examination Gloves (Blue)		
		₽ ₽
Indications for Use (Describe) A patient examination glove is a disposable device intended for fingers to prevent contamination between patient and examine	arme Free Nitrile Examination Gloves (Blue)  In for Use (Describe) It examination glove is a disposable device intended for medical purposes that is worn on the examiner's hands or so prevent contamination between patient and examiner.	
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	8	
Type of Use (Select one or both, as applicable)	AND THE STREET	
	<b>5</b> 1	

This section applies only to requirements of the Paperwork Reduction Act of 1995.

#### \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\*

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

## 510(k) SUMMARY 510(k) Number: K162113

#### 1.0 Submitter:

Nam Viet Glove Joint Stock Company, Hamlet 7, Phuoc Binh Commune, Long Thanh District 815300, Dong Nai Province, Vietnam.

 Phone No.
 :
 +84 08 3514 7788

 Fax No.
 :
 +84 08 3840 8506

 Contact Person :
 Ooi Loon Seng (Mdm)

 Email
 :
 Isooi@navigloves.com

Date of Preparation: 01 November 2016

#### 2.0 Name of the Device

Powder Free Nitrile Examination Gloves (Blue)

Common Name : Nitrile Patient Exam Gloves

Classification Name : Patient Examination Gloves (21 CFR 880.6250)

Product Code : Nitrile – LZA

#### 3.0 Identification of The Legally Marketed Devices That Equivalency is Claimed:

Predicate Device:

RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile)

Company: Riverstone Resources Sdn. Bhd.

510(K): K100603 Regulatory Class I Product Code: LZA

#### 4.0 Description of the Device:

The Powder Free Nitrile Examination Gloves (Blue) meets all the requirements of ASTM Specification D6319-10 - Standard Specification for Nitrile Examination Gloves for Medical Application.

#### 5.0 Intended Use of the Device

The Powder Free Nitrile Examination Glove (Blue) is a disposable device intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.

#### 6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Nitrile Examination Gloves (Blue) are summarized with the following technological characteristics and is substantially equivalent to the predicate device with regard to

physical characteristics, design, product features, and intended use. Both gloves are made with nitrile latex and meets ASTM Specification D6319-10 - Standard Specification for Nitrile Examination Gloves for Medical Application or equivalent standards.

CHARACTERISTICS	STANDARDS & ACCEPTANCE CRITERIA	DEVICE PERFORMANCE
Dimensions	ASTM D6319-10: Length: Size XS & S – min. 220mm Size M & L – min. 230mm	Meets ASTM D6319-10 Standard requirements Minimal Value for Length: 240mm
	Width – min. 95 ± 10mm	Minimal Value for Width: 93mm
Physical Properties	ASTM D6319-10:  Tensile Strength: Before Aging: 14 MPa After Aging: 14 MPa  Ultimate Elongation: Before Aging: min. 500% After Aging: min. 400%	Meets ASTM D6319-10 Standard requirements Tensile Strength: Before Aging: Minimal Value: 16.20 MPa After Accelerated Aging: Minimal Value: 16.16 MPa Ultimate Elongation: Before Aging Minimal Value: 661% After Aging Minimal Value: 630%
Thickness	ASTM D6319-10: Min. 0.05mm	Meets ASTM D6319-10 Standard requirements Palm – Minimal Value: 0.06mm Finger – Minimal Value: 0.13mm
D:	ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Pass (Under the conditions of the study, the test article is a non-irritant)
Biocompatibility	ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Pass (Under the conditions of the study, the test article is a non-sensitizer)
Freedom from Pinholes	21 CFR 800.20; ASTM D5151-06 AQL 2.5	Meets 21 CFR 800.20 and ASTM D5151-06 Standard requirements Passes AQL 2.5
Powder Residual	ASTM D6124-06: ≤2 mg / glove	Meets ASTM D6124-06 Standard requirements Minimal Value: 0.68 mg

#### 7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of non-clinical tests that support a determination of substantial equivalence is the same as described in section 6.0 above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL.

#### 8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed for gloves or most devices cleared by the 510(k) process.

### 9.0 Substantial Equivalence Comparison

The Powder Free Nitrile Examination Gloves (Blue) is substantially equivalent to the predicate device with respect to intended use, product features and the technological characteristics. The substantial equivalence comparison is presented in the table below:

Characteristic and parameters	Riverstone Resources Sdn. Bhd. K100603 RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile) (Predicate)	Powder Free Nitrile Examination Gloves (Blue) (Proposed) – K162113	Substantial Equivalence (SE)
Product Code	LZA	LZA	Same
Intended use	Intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Intended for medical purposes that is worn on the examiner's hands or fingers to prevent contamination between patient and examiner.	Same
Indications for Use Statement	ndications for Use   A powder free patient		Same
Device Material	Nitrile Synthetic Latex	Nitrile Synthetic Latex	Same
Color	Blue	Blue	Same
Additives	No flavor additive	No flavor additive	Same
Instruction For Use on Labeling	Single Use Only	Single Use Only	Same
Construction	Ambidextrous	Ambidextrous	Same
Sterility	Non-sterile	Non-sterile	Same
Acceptance Criteria	ASTM D6319-10	ASTM D6319-10	Same
Device Tolerances &	Specifications :		
Device Tolerances & Specifications:    Meets ASTM D6319-10		Meets ASTM D6319-10  Overall Length: Size XS & S - min. 220mm Size M & L - min. 230mm  Width (± 10mm) Size XS - 70mm Size XS - 70mm Size S - 80mm Size M - 95mm Size L - 110mm Size XL - 120mm  Thickness at Finger - min. 0.05mm	Same

#### Traditional 510(k) Premarket Notification Powder Free Nitrile Examination Gloves (Blue)

	Thickness at Palm – min. 0.05mm	Thickness at Palm – min. 0.05mm	
Physical Properties	Meets ASTM D6319-10:  Before Aging Tensile Strength – min. 14.0 MPa Ultimate Elongation – min. 500%	Meets ASTM D6319-10:  Before Aging Tensile Strength – min. 14.0 MPa Ultimate Elongation – min. 500%	
	After Aging Tensile Strength – min. 14.0 MPa Ultimate Elongation – min. 400%	After Aging Tensile Strength – min. 14.0 MPa Ultimate Elongation – min. 400%	
Biocompatibility Test a. Irritation Tests b. Skin Sensitization Tests	Under the conditions of the study, the test article is a non-irritant and non-sensitizer.	Under the conditions of the study, the test article is a non-irritant and non-sensitizer.	Same
Residual Powder test	Meets ASTM D6124-06: ≤2 mg / glove	Meets ASTM D6124-06	Same
Freedom from Holes	Meets ASTM D5151-06 AQL 2.5	Meets ASTM D5151-06 AQL 2.5	Same

#### 10.0 Conclusion

The Powder Free Nitrile Examination Gloves (Blue) meet all of the requirements of FDA-recognized consensus standards; ASTM D6319-10, ASTM D5151-06, ASTM D6124-06 and ISO 10993-10: 2010 and meet our labeling claims and pinhole acceptable quality level (AQL) as shown above.

There are no significant differences between the two products and are identical in terms of intended use, materials and performance.

The conclusion drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.

## CÔNG TY CP TM – DV – XNK VIÊN PHÁT

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

Số: 180801-VP/180000019/PCBPL-BYT

TP.HCM, ngày 01 tháng 08 năm 2018

# BẢN PHÂN LOẠI TRANG THIẾT BỊ Y TẾ

Kính gửi: Công ty Cổ phần Găng tay Nam Việt

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 tháng 10 năm 2016 của Bộ Y tế, quy định chi tết việc phân loại trang thiết bị y tế;

Căn cứ Thông tư số 42/2016/TT-BYT ngày 15 tháng 11 năm 2016 của Bộ Y tế, quy định thừa nhận kết quả phân loại trang thiết bị y tế;

Nguyên tắc được sử dụng để phân loại:

Quy tắc 5 – Trang thiết bị y tế không phải trang thiết bị y tế chẩn đoán in vitro

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

STT	Tên Trang thiết bị Y Tế	Chũng loại/ Mã sản phẩm	Hãng, nước sản xuất	Hãng, nước chủ sở hữu	Loại trang thiết bị y tế	Quy tắc sử dụng
1	Găng tay khám bệnh không bột (loại cao su tổng hợp) Powder free Nitrile examination gloves	NV-NPFEX / XS,S,M,L,XL &XXL	Công ty Cổ Phần Găng Tay Nam Việt - Việt Nam	Tay Nam	A	5
2	Găng tay khám bệnh không bột (loại cao su thiên nhiên) Powder free Latex examination gloves	NV-LPFEX / XS,S,M,L,XL &XXL	Công ty Cổ Phần Găng Tay Nam Việt - Việt Nam	Công ty Cổ Phần Găng Tay Nam Việt - Việt Nam	A	5

Giám đốc

CÔ PHẨN
THƯƠNG MẠI - DỊCH VỤ
- XUẤT NHẬP KHẨU
VIỆN PHÁT

HANGOC MINH PHONG

# SỞ Y TẾ ĐỒNG NAI

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

Số: 180000006/PCBSX-ĐN Tính Đồng Nai, ngày 11 tháng 09 năm 2018

# 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 GĂNG TAY NAM VIỆT
- 2. Địa chỉ: 23A NGUYÉN HỮU CẢNH, Phường 22, Quận Bình Thạnh, Thành phố Hồ Chí Minh (Sản xuất tại: CÔNG TY CỔ PHẦN GĂNG TAY NAM VIỆT; Địa chỉ: ẤP 07, Xã Phước Bình, Huyện Long Thành, Tỉnh Đồng Nai)
- 3. Điện thoai: 02835147788 Fax: ......
- 4. Số văn bản đề nghị của cơ sở: 240701/2018-VB Ngày: 29/08/2018
- 5. Tên trang thiết bị y tế cơ sở công bố sản xuất: GĂNG TAY KHÁM BỆNH KHÔNG BỘT (LOẠI CAO SU TỔNG HỢP) POWDER FREE NITRILE EXAMINATION GLOVES, GĂNG TAY KHÁM BỆNH KHÔNG BỘT (LOẠI CAO SU THIÊN NHIÊN) POWDER FREE LATEX EXAMINATION GLOVES

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	х
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	х
6	Văn bản phân công, bổ nhiệm người phụ trách chuyên môn của cơ sở sản xuất	х
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	х
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	х
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	х
11	Hồ sơ về kho tàng bảo quản trang thiết bị y tế	х
12	Hồ sơ về phương tiện vận chuyển trang thiết bị y tế	x

NGƯỜI TIẾP NHẬN HÒ SƠ



## PRODUCTS SPECIFICATION THÔNG SỐ SẨN PHẨM

1. Product Number and Description/ Số sản phẩm và mô tả :

Product Code Mã sản phẩm	Product Description  Mô tả sản phẩm	Design & Features Kiểu dáng và đặc trưng	Product Color Màu sản phẩm	Classification Phân loại
LPF-FT50-24Z	Non Sterile Chlorinated Powder Free Latex Examination Glove ( M= 5.0gm +/- 0.2gm ) Găng tay cao su y tế không bột ( M= 5.0g +/- 0.2g )	Finger Textured  Vân nhám đầu ngón tay  Beaded Cuff  Cuộn mép ở cổ tay  Ambidextrous  Không phân biệt mặt	Natural <i>Tự nhiên</i>	Class 1 <i>Cấp 1</i>
Material <i>Nguyên liệu</i>	Natural Rubber  Cao su tự nhiên			

- Physical Dimension/ Kích thước vật lý:
   Width and Length/ Chiều rộng và chiều dài:

Size Kích cỡ	Total Length (mm) Chiều dài tổng (mm)	Width (mm) Chiều rộng (mm)	Weight (gm) Weight (gm) <i>Khối lượng (g)</i>
X-Small  Cực nhỏ	Min 240 Tối thiểu 240	75 +/- 5	4.0 +/- 0.2
Small <i>Nhỏ</i>	Min 240 Tối thiểu 240	85 +/- 5	4.5 +/- 0.2
Medium Trung bình	Min 240 Tối thiểu 240	95 +/- 5	5.0 +/- 0.2
Large <i>Lón</i>	Min 240 Tối thiểu 240	106 +/- 5	5.5 +/- 0.2
X-Large Cực lớn	Min 240 Tối thiểu 240	115 +/- 5	6.0 +/- 0.2
Extra Extra-Large Siêu lớn	Min 240 Tối thiểu 240	>120	6.5 +/- 0.2

#### 2.2 Thickness (Single Wall)/ Độ dày (một lớp):

Location of Thickness Measurement  Vị trí đo độ dày	Single Wall Thickness (mm) Chiều dày một lớp (mm)	Reference Standard Tiêu chuẩn tham khảo
Palm (at center of palm) Lòng bàn tay ( tại điểm giữa của lòng bàn tay)	Min 0.08	ASTM D 3578
Fingertip (at 13mm from the extreme tip) Đầu ngón tay (cách 13mm tính từ đỉnh ngón giữa)	Min 0.08	ASTM D 3578

3. Physical Properties/ Tính chất vật lý:

Characteristics Đặc tính	Reference Standard Tiêu chuẩn tham khảo	Before Ageing Trước lão hóa	After Ageing 7 days @ 70°C ± 2 hours Sau lão hóa 7 ngày (ở 70°C) ± 2 giờ
Force at Break (N) Lực căng tối đa (N)	En 455, Part 2	Min 6 (N)	Min 6 (N)
Tensile Strength (MPa) Sức căng kéo dài (MPa)	ASTM D 3578	Min 18 Mpa	Min 14 Mpa
Elongation at Break (%) Độ léo dài tối đa (%)	ASTM D 3578	Min 650%	Min 500%



## PRODUCTS SPECIFICATION THÔNG SỐ SẢN PHẨM

4. Quality Assurance/ Đảm bảo chất lượng:

Characteristics Đặc tính	Inspection Level & Sampling Plan  Mức độ kiểm tra & và kế hoạch lấy  mẫu	AQL & Acceptance Limit AQL & Giới hạn chấp nhận
Pinhole (Reference EN 455-1) Lỗ rò (tham khảo EN 455-1)	G-1 (Single Sampling)	AQL 1.5
Visual Major Defects  Lỗi trực quan chính	G-1 (Single Sampling)	AQL 2.5
Visual Minor Defects  Lỗi trực quan nhỏ	G-1 (Single Sampling)	AQL 4.0
Physical Dimension  Kích thước vật lý	S-2	AQL 4.0
Powder Residual Limit Giới hạn dư lượng bột	As per ASTM D6124-06 Test  Method  Phương pháp kiểm tra theo như  ASTM D6124-06	Below 2mg/glove Dưới 2mg/ găng
Water Extractable Protein	As per ASTM D5712-15 Test  Method  Phương pháp kiểm tra theo như  ASTM D5712-15	Below 50μg/ dm² <i>Dưới 50μg/ dm²</i>

5. Shelf Life/ Thời gian sống: Under normal storage condition, gloves shall have a shelf life of minimum 3 years from date of manufacture. Dưới điều kiện kho thông thường, găng tay sẽ có thời gian sống tối thiểu 3 năm kể từ ngày sản xuất.

6. Suggested Storage Condition/ Điều kiện kho được đề nghị:

Storage Condition Điều kiện kho	
Temperature range Phạm vi nhiệt độ	Recommended storage temperature shall not exceed 40 degrees Celsius. Recommended temperature is between 20 to 25 degrees Celsius.  Nhiệt độ kho được để nghị sẽ không vượt quá 40°C. Nhiệt độ tối ưu được để nghị nằm trong khoảng 20-25°C.
Humidity range Phạm vi độ ẩm	Prolong storage humidity shall not exceed 50%. Độ ẩm kho được kỳ vọng không vượt quá 50%.
Sunlight effect Ảnh hưởng của ánh nắng Mặt Trời	Keep away from sunlight. Sunlight could cause discoloration and long exposure could severely reduce physical properties of gloves.  Giữ tránh ánh nắng mặt trời. Ánh nắng có thể là nguyên nhân làm mất màu sắc và phơi bày trong thời gain dài có thể làm giảm mạnh tính chất vật lý của găng tay.



#### NAM VIET GLOVE JOINT STOCK COMPANY

HEAD OFFICE: 23A NGUYEN HUU CANH STREET, WARD 22, BINH THANH DISTRICT, HO CHI MINH CITY, VIETNAM

This is a must-site consticute, additional site(s) are letted on the resd page(s).

Bureau Vertas Certification Holding SAS - UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the Management System standards detailed below.

Standard

#### ISO 9001:2015

Scope of certification

MANUFACTURE OF NON STERILE POWDER FREE LATEX AND NITRILE EXAMINATION GLOVES FOR USE IN THE MEDICAL, **FOOD AND INDUSTRIAL SECTORS** 

Original cycle start date:

01 March 2016

Expiry date of previous cycle:

28 February 2019

Recertification Audit date:

Recertification cycle start date:

23 August 2018 14 September 2018

Subject to the continued satisfactory operation of the organization's Management

System, this certificate expires on:

28 February 2022

Certificate no.: VN.4277793/Q Version: 1 Revision date: 14 September 2018

**NGUYENTU HAI** 

UKAS

0008

Certification body address: 5" Place, 66 Prescrit Street, Landan, £1 th10, United Ringdon. LOCK OTHICK CHE 4.4A, 4th Piber, 2-Town 1 dialong 364 Cong Hos Street. Ten Birth Dilance, Ho Chi Minn City, Vietnam

> Further clarifications regarding the scope of this partificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check his continue valety, pause cut +64-26-38/2 2246.

> > Page 1 of 2



#### NAM VIET GLOVE JOINT STOCK COMPANY

Standard

#### ISO 9001:2015

Scope of certification

HEAD OFFICE: MANUFACTURING MANAGEMENT OF NON STERILE POWDER FREE LATEX AND NITRILE EXAMINATION GLOVES FOR USE IN THE MEDICAL, FOOD AND INDUSTRIAL SECTORS

1	Site Name/ Location	Site addition Date	Site Address	Site Scope
	FACTORY	01 March 2016	HAMLET 7, PHUOC BINH COMMUNE, LONG THANH DISTRICT, DONG NAI PROVINCE, VIETNAM	MANUFACTURE OF NON STERILE POWDER FREE LATEX AND NITRILE EXAMINATION GLOVES FOR USE IN THE MEDICAL, FOOD AND INDUSTRIAL SECTORS

Certificate no: VN.4277793/Q Version: 1 Revision date: 14 September 2018

**NGUYEN TU HAI** 



Lint 4.4A 4th Foor E-Town 1 Building 354 Cong Hou Street, Tax Birth Dietrict Ho Ohr Miles Only Webnam Further clarifications regarding the scope of this certificals and the applicability of the Management System requirements may be sittaked by consulting the organization. To check this certificate validity please cell +84-29-3812 2246.

Contilication body address: 5th Noon, 66 Prescot Street, London, ET 94G, Lodent Hingdon

Page Z of 2



## NAM VIET GLOVE JOINT STOCK COMPANY

Head Office and Operative Site: 23A Nguyen Huu Canh, Binh Thanh District, Ho Chi Minh City, Vietnam

Operative Unit: Hamlet 7, Phuoc Binh Commune, Long Thanh District, Dong Nai Province, Vietnam

Bureau Veritas Italia S.p.A. certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

Standard

# EN ISO 13485:2016

Scope of certification

Manufacture of non sterile powder free latex and nitrile examination gloves.

Certification awarded in conformity with the requirements of ACCREDIA DT 02-DC REV.00

Certification cycle start date: 31 January 2019

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 01 February 2022

Original certification date: 02 February 2016

Certificate No. IT287017

Version N.1 Revision date: 31 January 2019

ANDREA FILIPPI - Local Technical Manager

Certification body address: Bureau Veritas Italia spa, Viale Monza , 347, 20126 Milano, Italia

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website http://www.bureauveritas.it/certificate

ACCREDIA \$



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Notified Body 0321

Issued to: Nam Viet Glove Joint Stock Company

23A Nguyen Huu Canh Ward 22, Binh Thanh District

Ho Chi Minh City

Vietnam

SATRA Client: P1727

# EC Type-Examination Certificate

#### Number 8915 Issue 1

Date first issued: 03/08/2017

This is to certify that the product group reference "NPF-FT30-24, NPF-FT35-24, NAG-FT37-24, NPF-FT40-24, NPF-FT55-24" comprising the following products:

**Product Reference** 

Description

NPF-FT30-24 NPF-FT35-24 Five Finger Powder Free Nitrile Gloves

NAG-FT37-24 NPF-FT40-24 NPF-FT55-24BK

Classification

Sizes: S, M, L XL 

 EN ISO 374-1:2016 (Type C)
 Level
 EN 374-4:2013

 Sodium hydroxide 40%
 6
 11.8%

 Sulphuric acid 50%
 6
 4.4%

 Formaldehyde 37%
 2
 43.0%

EN 374-5:2016

Protection against bacteria and

ena anu

fungi

Protection against viruses

N/A

Pass

#### Technical reports:

SATRA: SPC0257773/1721, CHM0255399/1711/SMcD, CHM0257912/1721/SMcD/B, CHM0257912/1721/SMcD/A

has been subject to an EC Type-examination in accordance with Article 10 of the PPE Directive (89/686/EEC) and has been shown to satisfy the relevant provisions of this Directive for the complex category through:

- i Testing to the following standard: EN ISO 374-1:2016; EN420:2003+A1:2009
- ii Examination of the relevant technical documentation.

You are therefore licensed to mark the product(s) listed above in accordance with Article 13 of Directive (89/686/EEC) and any relevant amending Directives once you have drawn up an EC declaration of product conformity. Please note that:

- 1. Full details of the certification and product are contained in the manufacturer's technical file
- 2. This certificate is issued subject to the conditions on the reverse side of this certificate
- CE Marking of production is also reliant on current compliance with Directive 89/686/EEC Article 11
- 4. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text

Signed:

Carabollo (Tara Holly)

Date 03/08/2017

Signed:

On behalf of SATRA

**CONDITIONS AND NOTES** 

1. CARE AND PROTECTION OF CERTIFICATES

This certificate shall be kept together with the relevant technical files 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 (in the UK, this will be Trading Standards

Department of Local Authorities) and these must be produced within the specified time.

2. EXPIRY OF CERTIFICATES

This certificate relates only to the condition of the testable items at the time of the certification

procedure. This certificate will cover the product until such a time that any of these conditions are

changed. The certificate therefore does not have an expiry date.

WITHDRAWAL OF CERTIFICATES

SATRA Technology Centre 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 the PPE directive.

LOSS OF CERTIFICATES

If you lose this certificate you can get a duplicate from SATRA Technology Centre for a minimal

charge by quoting details such as the approximate date of issue and the product reference.

PPE Doc 13/14 Issue 1



SATRA Technology Centre Ltd Wyndham Way, Telforc Way, Kettering, Northamptonshire, NN16 8SD United Kingdom Tel: +44 (0) 1536 410000 Fax +44 (0) 1536 410626 email: info@setra.com

www.satra.com



Customer details: Nam Viet Glove Joint Stock Company

23a Nguyen Huu Canh St

Ward 22

Binh Thanh District

HCMC Vietnam

For the attention of: Ooi Loon Seng

SATRA reference: CHM0255399/1711/

SMcD

Your reference:

Date of report: 19th April 2017

Samples received: 20th March 2017

Date(s) work

carried out:

28th March to 18th April

2017

## **TECHNICAL REPORT**

Subject: BS EN 16523-1:2015 resistance to permeation by chemicals on gloves

described as Nitrile Powder Free Gloves, Product code: NPF-FT30-24LB-03 against 40% sodium hydroxide, 50% sulphuric acid and 37% formaldehyde

#### 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:

S McDonald

Position:

Chemical Technologist

Department:

Chemical & Analytical Technology

(Page 1 of 7)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3856296 at the above address.





#### WORK REQUESTED:

Samples of gloves described as Nitrile Powder Free Gloves, Product code: NPF-FT30-24LB-03 were received on the 20<sup>th</sup> March 2017 for testing in accordance with BS EN 16523-1:2015 and assessment in accordance with the requirements of BS EN ISO 374-1: 2016.

#### CONCLUSION:

When assessed in accordance with the requirements of BS EN ISO 374-1:2016 the samples of gloves described as Nitrile Powder Free Gloves, Product code: NPF-FT30-24LB-03 achieved the following performance levels:

Chemical	Performance level
40% sodium hydroxide (CAS: 1310-73-2)	6
50% sulphuric acid (CAS: 7664-93-9)	6
37% formaldehyde (CAS: 50-00-0)	2

Full results are reported in the following tables.

#### **TESTING REQUIRED:**

BS 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:

BS 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)	
001 00	>10	
2	>30	
3	>60	
4	>120	
5	>240	
6	>480	

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

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0255399/1711/SMcD

Date: 19<sup>th</sup> April 2017

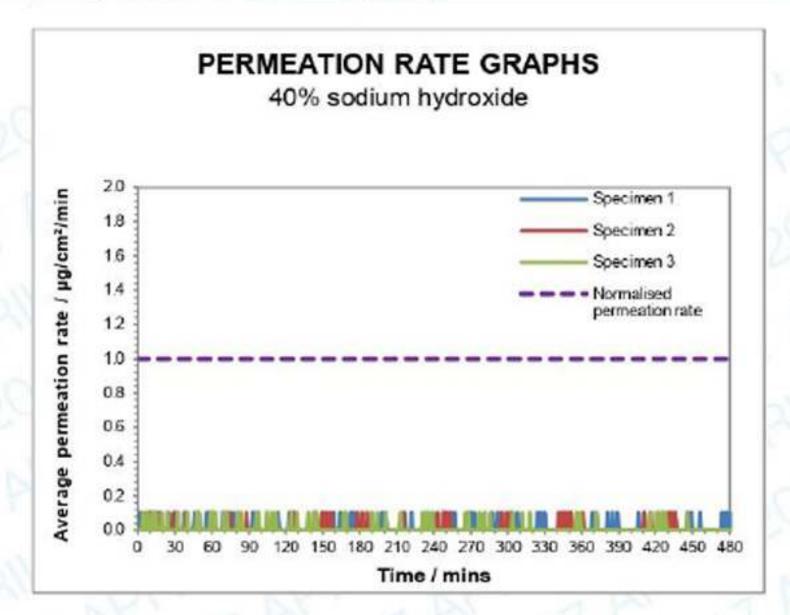
Signed:

(Page 2 of 7)





Test/Property	Sample reference:	Nitrile Powder Free Gloves, Product code: NPF- FT30-24LB-03		Performance
		Chemical: 40% sodium hydroxide		
		Normalised permeation rate (NPR): 1 µg/cm²/min		
BS EN	Test	Detection technique:	Conductimetry (continuous measurement)	
16523-1:2015	information:	Collection medium: De	eionised water (closed loop)	
in accordance with SATRA		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
SOP CAT-009	7	Test temperature:	(23 ± 1) °C	Level 6
Using PTFE	Specimen	Thickness (mm)∆	Breakthrough time (mins)	
permeation cells with standardised	1	0.07	>480	
dimensions		0.06	>480	
	3	0.06	>480	
		Test result:	>480	
		UoM:	± <1	
Visual appe specimens a			Discoloured	



Nam Viet Glove Joint Stock Company SATRA Reference: CHM0255399/1711/SMcD

Date:

19th April 2017

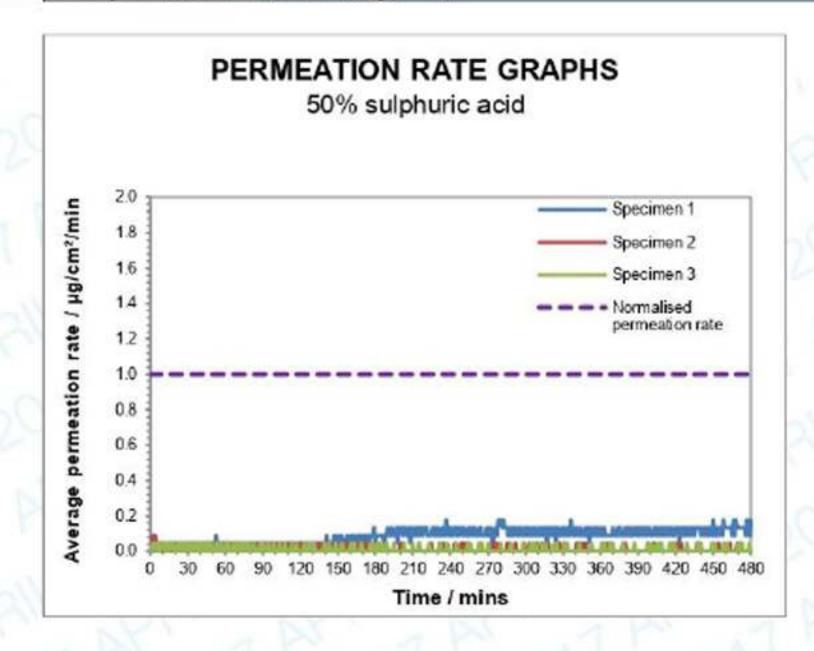
(Page 3 of 7)

Signed:





Test/Property	Sample reference:		loves, Product code: NPF- -24LB-03	Performance
		Chemical: 5	0% sulphuric acid	
		Normalised permeation rate (NPR): 1 µg/cm²/min		
BS EN	Test	Detection technique: Conductimetry (continuous measurement)		
16523-1:2015	information:	Collection medium: De	eionised water (closed loop)	
in accordance with SATRA	7	Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
SOP CAT-009	1	Test temperature:	(23 ± 1) °C	Level 6
Using PTFE	Specimen	Thickness (mm)∆	Breakthrough time (mins)	
permeation cells with standardised	1	0.06	>480	
dimensions	2	0.06	>480	
	3	0.06	>480	
		Test result:	>480	
		UoM:	± <1	
Visual appearance of specimens after testing:			Discoloured	



Nam Viet Glove Joint Stock Company

SATRA Reference:

CHM0255399/1711/SMcD

Date:

19th April 2017

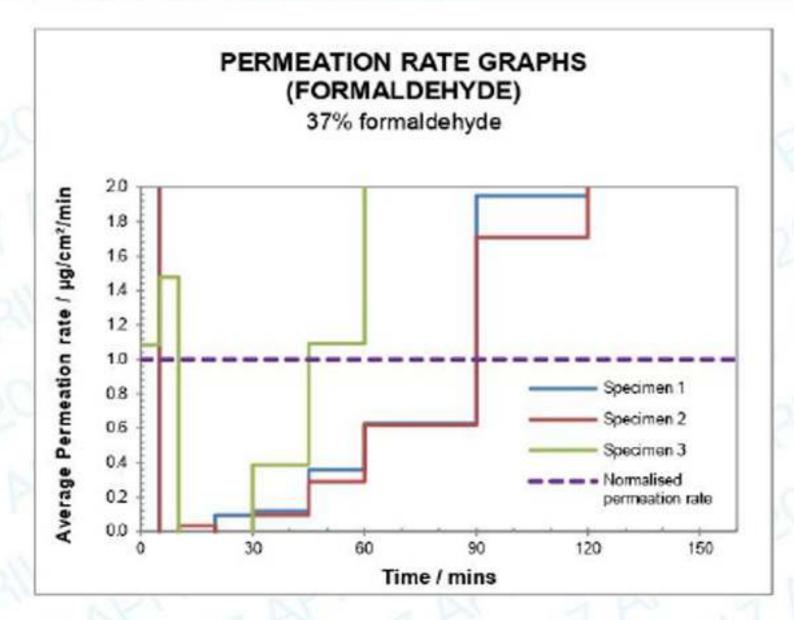
(Page 4 of 7)

Signed: S.M. Dand I





Test/Property	Sample reference:		oves, Product code: NPF- -24LB-03	Performance
		Chemical: 3	7% formaldehyde	
	4	Normalised permeation rate (NPR): 1 µg/cm²/min		
BSEN	Test	Detection technique:	Spectrophotometry (periodic measurement)	
16523-1:2015	information:	Collection medium: De	eionised water (closed loop)	
in accordance with SATRA		Collection medium stirri (each cell constant to within		
SOP CAT-025		Test temperature:	(23 ± 1) °C	Level 2
Using PTFE	Specimen	Thickness (mm)△	Breakthrough time (mins)▼	
permeation cells with standardised	1	0.07	Between 91 and 120	
dimensions		0.07	Between 91 and 120	
	3	0.06	Between 46 and 60	
		Test result:	Between 46 and 60	
		UoM:	See note below	
Visual appe specimens a			No change	



The high readings at 0-10 minutes were deemed to be outliers and do not represent chemical breakthrough.

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

For SOP CAT-025, where both the P<sub>1</sub> and P<sub>u</sub> 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.

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0255399/1711/SMcD

Date: 19th April 2017

Signed:

(Page 5 of 7)





- BS 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 BS EN 16523-1:2015 is not possible.

#### APPENDICES:



Gloves described as Nitrile Powder Free Gloves, Product code: NPF-FT30-24LB-03

Nam Viet Glove Joint Stock Company SATRA Reference: CHM0255399/1711/SMcD Date: 19<sup>th</sup> April 2017

(Page 6 of 7)

Signed: S.M. Dandld





#### TERMS AND CONDITIONS OF BUSINESS

#### GENERAL

Work done or services undertaken are subject to the terms and conditions detailed below and all other conditions, warranties and representations, expressed or implied are hereby excluded.

#### 2. PRICES

Prices are based on current material and production costs, exchange rates, duty and freight and are subject to change without notice.

#### 3. DELIVERY ESTIMATES

Delivery estimates are made in good faith and date from receipt of a written order and full information to enable us to proceed. While SATRA or its subsidiaries (hereafter referred to as "SATRA") make every effort to fulfil them, such estimates are subject to unforeseen events and if not maintained, cannot give rise to any claim. Offers "ex stock" are subject to prior sale.

#### CANCELLATION AND RETURNS

Cancellation of orders for goods, services, training or consultancy is only acceptable by prior agreement of SATRA and a charge will normally be made.

#### CLAIMS

Claims for errors, shortages etc should be notified within 10 days of date of receipt. In the event of goods damaged in transit, packing materials should be retained for examination; otherwise no liability can be accepted.

#### PAYMENT TERMS

Payment terms are net 21 days from date of invoice. Failure to comply with the terms of payment may result in delayed delivery of goods and services and a review of the Customer's credit account. Should the customer become subject to an administration order, or becomes bankrupt or goes into liquidation, SATRA has a right to cancel any contract and discontinue any work. SATRA reserves the right to adjust US Dollar and Euro sales price where customer exceeds credit terms and where the exchange rate has moved more than 10% since invoicing.

#### RETENTION OF TITLE

All goods remain the property of SATRA until paid in full. Under no circumstances will a customer's purchase order override SATRA's Retention of Title clause. In the case of software, the ownership of the software remains with SATRA. Payment of invoices in full will entitle the customer to use the software under licence until (a) they cease to be a member of SATRA or (b) they cease trading. In both instances, the licence shall then revert to SATRA.

#### GUARANTEE

All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.

#### 9. TEST REPORTS

Results given in test reports refer only to samples submitted for analysis and tested by 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. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.

#### TEST SAMPLES

Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.

#### RESPONSIBILITY

Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.

#### 12. CONFIDENTIALITY

Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:

- The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
- iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.

#### CONSTRUCTION AND ARBITRATION

The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0255399/1711/SMcD

Date: 19th April 2017

(Page 7 of 7)

Signed: S.M. Dand



For the attention of:

#### 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.com www.satra.com



Customer details: Nam Viet Glove Joint Stock Company

23a Nguyen Huu Canh St

Ward 22

Binh Thanh District

Ooi Loon Seng

HCMC Vietnam SATRA reference: CHM0257912/1721/

SMcD/A

Your reference:

Date of report: 9th June 2017

Samples received: 16th May 2017

Date(s) work

2<sup>nd</sup> to 8<sup>th</sup> June 2017 carried out:

# TECHNICAL REPORT

Chemical innocuousness testing in accordance with BS EN 420: 2003 + A1: Subject:

2009 on gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue

#### 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.

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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:

S McDonald

Position:

Chemical Technologist

Department:

Chemical & Analytical Technology

(Page 1 of 4)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3856296 at the above address

# SATRA

# **TECHNICAL REPORT**



#### WORK REQUESTED:

Samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue were received on the 16th May 2017 for testing in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 Protective Gloves - General Requirements and Test Methods.

#### MATERIALS TESTED:

NPF-FT30-24LB Powder free nitrile gloves-blue

#### CONCLUSIONS:

The samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue were assessed in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and were found to meet with the requirement for pH value.

As required under clause 4.3.1 General innocuousness of protective gloves, the samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue were found to meet the REACH annex XVII requirement for PAHs.

Full results are reported in the following tables.

#### TESTS REQUIRED:

- BS EN 420:2003 Clause 4.3.2 pH Value (ISO 3071 for Textiles & other materials & ISO 4045 for leathers)
- #SATRA SOP CAT-018 Determination of PAHs (based on ZEK 01.4-08)

## **RESULTS AND REQUIREMENTS:**

BS EN 420:2003 + A1: 2009 Clause 4.3.2 pH value

Date of determination: 2<sup>nd</sup> June 2017

Sample	Method	pH Value	UoM	Pass/Fail
NPF-FT30-24LB Powder free nitrile gloves-blue	ISO 3071:2005 (water extraction)	7.6	± 0.1	Pass
Requirement	pH value greater t	han 3.5 and les	s than 9.5	11/2 11

The extraction solution temperature was 25°C and at pH 7.1

Nam Viet Glove Joint Stock Company SATRA Reference: CHM0257912/1721/SMcD/A

Date: 9th June 2017 (Page 2 of 4)

Signed:

5.M. Donald





## ≠SATRA SOP CAT-018 - Determination of PAHs

Analysed by Gas Chromatography with Mass Spectrometry (GC-MS)

Sample	PAHs detected (mg/kg)	Pass/Fail
NPF-FT30-24LB Powder free nitrile gloves-blue	<0.2 (of each PAH listed in the appendices)	Pass
Requirements: REACH 1907/2006 annex XVII entry number 50	<1mg/kg of each PAH listed in the appendices	_

#### APPENDICES:

REACH Regulation (EC) No 1907/2006 Annex XVII entry number 50 as amended by regulation 1272/2013

PAH	CAS Number	Requirements		
Benzo[a]anthracene	56-55-3	Articles shall not be placed on the market for		
Chrysene	218-01-9	supply to the general public, if any of their		
Benzo[b]fluoranthene	205-99-2	rubber or plastic components that come into		
Benzo[k]fluoranthene	207-08-9	direct as well as prolonged or short-term		
Benzo[j]fluoranthene	205-82-3	repetitive contact with the human skin or the		
Benzo[e]pyrene	192-97-2	oral cavity, under normal or reasonably		
Benzo[a]pyrene	50-32-8	foreseeable conditions of use, contain more		
Dibenzo[a,h]anthracene	53-70-3	than 1 mg/kg of any of the listed PAHs.		



Gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue

Nam Viet Glove Joint Stock Company SATRA Reference: CHM0257912/1721/SMcD/A

9th June 2017 Date:

(Page 3 of 4)

Signed:

# SATRA

# **TECHNICAL REPORT**



#### TERMS AND CONDITIONS OF BUSINESS

#### GENERAL

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#### PRICES

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#### RETENTION OF TITLE

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All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.

#### TEST REPORTS

Results given in test reports refer only to samples submitted for analysis and tested by 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. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.

#### 10. TEST SAMPLES

Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.

#### 11. RESPONSIBILITY

Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.

#### 12. CONFIDENTIALITY

Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:

- The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
- iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.

#### CONSTRUCTION AND ARBITRATION

The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0257912/1721/SMcD/A

Date: 9th June 2017 (Page 4 of 4)

Signed: S.M. Dand I



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.com www.satra.com



Customer details: Nam Viet Glove Joint Stock Company

23a Nguyen Huu Canh St

Ward 22

Binh Thanh District

HCMC Vietnam

For the attention of: Ooi Loon Seng

SATRA reference: CHM0257912/1721/

SMcD/B

Your reference:

Date of report: 9th June 2017

Samples received: 16th May 2017

Date(s) work

6th June 2017 carried out:

# TECHNICAL REPORT

Subject: BS EN 374-4: 2013 determination of resistance to degradation by chemicals on

gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue

#### 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%.

S McDonald Report signed by:

Chemical Technologist Position:

Chemical & Analytical Technology Department:

(Page 1 of 5)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3856296 at the above address





#### WORK REQUESTED

Samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue were received on the 16th May 2017 for testing in accordance with BS EN 374-4:2013. Full results are given below.

#### CONCLUSION:

When assessed in accordance with BS EN 374-4:2013 the samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue achieved the following degradation results:

Chemical	Mean degradation / %	
Formaldehyde (CAS: 50-00-0)	43.0	
40% Sodium hydroxide (CAS: 1310-73-2)	11.8	
96% Sulphuric acid (CAS: 7664-93-9)	100.0	

NOTE: The quoted mean degradation values are subject to often significant measurement uncertainties. Please see results tables below for more information

#### **TESTING REQUIRED:**

BS EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4: Determination
of resistance to degradation by chemicals.

## RESULTS:

Sample description:	NPF-FT30-24LB Powder free nitrile gloves-blue			
Challenge chemical:	Formaldehyde (CAS: 50-00-0)			
Test temperature / °C:	11/1/1	10, 7 10,		
Degradation 10/	Glove 1	Glove 2	Glove 3	
Degradation / %:	41.7	56.1	31.1	
Mean degradation (DR) / %:	INTE INF	43.0	70	
Standard deviation (σ <sub>DR</sub> ) / %:	2001/20	12.5	01,1250	
UoM + / ± %:	The Walter	21.5	11 11 11 11 11 11	
Appearance of samples after testing:	No change		2017 00	

Nam Viet Glove Joint Stock Company

SATRA Reference:

CHM0257912/1721/SMcD/B

Date: 9<sup>th</sup> June 2017

(Page 2 of 5)

Signed: S.M.Donald.





Sample description:	NPF-FT30-24LB Powder free nitrile gloves-blue				
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)				
Test temperature / °C:	(23 ± 1)				
Dogradation / 9/ .	Glove 1	Glove 2	Glove 3		
Degradation / %:	-14.2	34.9	14.7		
Mean degradation (DR) / %:		11.8			
Standard deviation (σ <sub>DR</sub> ) / %:		24.7			
UoM + / ± %:		27.1			
Appearance of samples after testing:		No change			

Sample description:	NPF-FT30-24LB Powder free nitrile gloves-blue			
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)			
Test temperature / °C:	(23 ± 1)			
Danuadatian (9)	Glove 1	Glove 2	Glove 3	
Degradation / %:	100.0	100.0	100.0	
Mean degradation (DR) / %:	2001,53	100.0	20 182	
Standard deviation (σ <sub>DR</sub> ) / %:	Mr. Mar	0.0	1 300	
UoM + / ± %:	-011 -011	16.7	200	
Appearance of samples after testing:	THE WIT	Discoloured and degraded	A INTO	

Absolute measurement uncertainty of the mean degradation value; it is therefore inferred that the true degradation value, with 95% confidence, lies within the range (DR ± UoM) %.

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0257912/1721/SMcD/B

Date: 9th June 2017

(Page 3 of 5)

Signed: S.M. Dand M





## APPENDICES:



Gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue

Nam Viet Glove Joint Stock Company

SATRA Reference: Date: CHM0257912/1721/SMcD/B

9th June 201

Signed:

Page 4 of 5)





#### TERMS AND CONDITIONS OF BUSINESS

#### GENERAL

Work done or services undertaken are subject to the terms and conditions detailed below and all other conditions, warranties and representations, expressed or implied are hereby excluded.

#### 2. PRICES

Prices are based on current material and production costs, exchange rates, duty and freight and are subject to change without notice.

#### 3. DELIVERY ESTIMATES

Delivery estimates are made in good faith and date from receipt of a written order and full information to enable us to proceed. While SATRA or its subsidiaries (hereafter referred to as "SATRA") make every effort to fulfil them, such estimates are subject to unforeseen events and if not maintained, cannot give rise to any claim. Offers "ex stock" are subject to prior sale.

#### 4. CANCELLATION AND RETURNS

Cancellation of orders for goods, services, training or consultancy is only acceptable by prior agreement of SATRA and a charge will normally be made.

#### CLAIMS

Claims for errors, shortages etc should be notified within 10 days of date of receipt. In the event of goods damaged in transit, packing materials should be retained for examination; otherwise no liability can be accepted.

#### PAYMENT TERMS

Payment terms are net 21 days from date of invoice. Failure to comply with the terms of payment may result in delayed delivery of goods and services and a review of the Customer's credit account. Should the customer become subject to an administration order, or becomes bankrupt or goes into liquidation, SATRA has a right to cancel any contract and discontinue any work. SATRA reserves the right to adjust US Dollar and Euro sales price where customer exceeds credit terms and where the exchange rate has moved more than 10% since invoicing.

#### RETENTION OF TITLE

All goods remain the property of SATRA until paid in full. Under no circumstances will a customer's purchase order override SATRA's Retention of Title clause. In the case of software, the ownership of the software remains with SATRA. Payment of invoices in full will entitle the customer to use the software under licence until (a) they cease to be a member of SATRA or (b) they cease trading. In both instances, the licence shall then revert to SATRA.

#### B. GUARANTEE

All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.

#### TEST REPORTS

Results given in test reports refer only to samples submitted for analysis and tested by 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. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.

#### 10. TEST SAMPLES

Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.

#### 11. RESPONSIBILITY

Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.

#### CONFIDENTIALITY

Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:

- i. The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
- iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.

#### CONSTRUCTION AND ARBITRATION

The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009

Nam Viet Glove Joint Stock Company

SATRA Reference: CHM0257912/1721/SMcD/B

Date:

9th June 2017

(Page 5 of 5)

Signed: SM Dand Id



#### 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.com

www.satra.com



Customer details: Nam Viet Glove Joint Stock Company SATRA reference: CHM0259430/1727/CI

23a Nguyen Huu Canh St

Ward 22

Binh Thanh District

HCMC Vietnam

For the attention of: Ooi Loon Seng

14th July 2017 Date of report:

Samples received: 161n May 2017

11th July 2017 Date(s) work

carried out:

Your reference:

## TECHNICAL REPORT

Subject: BS EN 374-4:2013 determination of resistance to degradation by chemicals on

gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue against

50% Sulphuric acid

#### 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:

Charlotte Lovell

Position:

Chemical Technologist

Department:

Chemical & Analytical Technology

(Page 1 of 5)







#### WORK REQUESTED:

Samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue were received on the 16<sup>th</sup> May 2017 for testing in accordance with BS EN 374-4:2013. Full results are given below.

#### CONCLUSION:

When assessed in accordance with BS EN 374-4:2013 the samples of gloves described as NPF-FT30-24LB Powder free nitrile gloves-blue achieved the following degradation results:

Chemical	Mean degradation / %
50% Sulphuric acid (CAS: 7664-93-9)	4.4

NOTE: The quoted mean degradation values are subject to often significant measurement uncertainties. Please see results tables below for more information

#### TESTING REQUIRED:

BS EN 374-4:2013. Protective gloves against chemicals and micro-organisms. Part 4:
 Determination of resistance to degradation by chemicals.

#### RESULTS:

Sample description:	NPF-FT30-24LB Powder free nitrile gloves-bl			
Challenge chemical:	50% Sulphuric acid			
Test temperature / °C:	(23 ± 1)			
Downadation (9/)	Glove 1	Glove 2	Glove 3	
Degradation / %:	-0.2	14.2	-1.0	
Mean degradation (DR) / %:	4.4		n	
Standard deviation (σ <sub>DR</sub> ) / %:	8.5		117	
UoM + / ± %:	19.3		7 70- 4	
Appearance of samples after testing:	-071	Softened	10-01	

 Absolute measurement uncertainty of the mean degradation value; it is therefore inferred that the true degradation value, with 95% confidence, lies within the range (DR ± UoM) %.

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

Nam Viet Glove Joint Stock Company SATRA Reference: CHM0259430/1727/CL

Date: 14th July 2017

Signed:

(Page 2 of 5)







Sample described as NPF-FT30-24LB Powder free nitrile gloves-blue

Nam Viet Glove Joint Stock Company

Date:

Signed:





	TERMS AND CONDITIONS FOR THE SALE OF GO	ODS A	ND/OR THE PROVISION OF SERVICES
1.	GENERAL		
		4.	SUSPENSION OR TERMINATION OF SERVICES
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.	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.
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.	42	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 discumstances 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
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.		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.
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.	5.	LIABILITY AND INDEMNIFICATION
1.5	All references in these terms and conditions to:	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
(8)	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		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 autocontractors 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.
(b)	"Services" are the work or services to be supplied or performed under the Contract (including where		of unclear, erroneous, incomplete, misleading or talse information provided to SATRA
(c)	relevant the supply of software, components and consumables); and "Goods" are the equipment, consumables or other physical items sold under the Contract (including	5.2	Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
	documents, drawings or other information required in order to operate the equipment).	(a)	death or personal injury caused by its negligence or the negligence of its employees or agents;
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.	(b) (d) (e)	fraud or fraudulent misrepresentation; breach of the terms implied by Section 12 of the Sale of Goods Act 1979; defective products under the Consumer Protection Act 1987; or any other liability which cannot be limited or excluded by applicable law.
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.	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
2.	FEES AND PAYMENT		of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
2.1	Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are not 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.	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
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.	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.
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	6.2	During the course of providing the Goods or Services and for a period of one year thereafter the Client
	may change as a result of circumstances out of SATRA's control.		shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
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.	6.3	The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
2.5	Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.	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.
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 mories 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 prejudios to any of	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.
2.7	SATRA's accrued rights.  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.	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
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.		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.
4.5	Selective and the selection of the selec	7.	CONFIDENTIALITY
2.9	SATRA reserves the right to tring 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.	7.1	Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables induction, reports, adultos drawings, photographs, apacifications

- 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 Ciert 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

- 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 fall 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 perty 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 Charteres 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, upless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Academy and the Controlled Cost Rules of

Nam Viet Glove Joint Stock Company
SATRA Reference: CHM0259430/1727/CL
Date: 14<sup>th</sup> July 2017

unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

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

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

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 certrication marks lies solely

All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in

whetever medium) produced by SATRA pursuent to this Contract shall belong to SATRA. The Client shall

The Client agrees and advnowledges 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

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

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

have the right to use said material in accordance with the terms of this Contract.

provided by SATRA to the Client) and the provision of the Services to the Client.

INTELLECTUAL PROPERTY RIGHTS

time for an additional fee.

(Page 4 of 5)

Signed: (del)





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

the Chartered Institute of Arbitistore (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. 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.

#### 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.
- 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 fulfi them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any daim. Time will not be of the essence in relation to the performance
- 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.
- SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to diadose all information required to undertake the Services.
- Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Olient 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.
- 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 cases 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, aamples 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.

- 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.
- 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.
- 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.

#### CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES 11.

- The Client shall provide aufficient 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.
- 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.
- 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.
- Where the Client falls to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has compiled and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

#### DELIVERY AND NON-DELIVERY OF GOODS

- 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.
- Should expedited delivery be requested and agreed, SATRA shall be entried to make additional charges to cover overtime or any other additional costs.
- 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.
- 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.
- 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.
- 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, I censes 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).

#### RISK/TITLE OF GOODS

- Subject to dause 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 incoferms 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
- The Company shall not accept responsibility for loss or damage in transit unless.
- 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
- 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.

- Title to the Goods shall not pass to the Client until the earlier of when:
- 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
- the Client resets the Goods in accordance with clause 13.5 in which case title shall pass to the Client b) immediately before the time at which the resale by the Client occurs.
- Until ownership of Goods has passed to the Client, the Client shall:
- hold the Goods as SATRA's ballee;
- store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third Di 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);
- not destroy, defece or obscure any identifying mark or packaging on or relating to the Goods; and 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.
- 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.
- 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:
- the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; 0)
- 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
- if the Client fails to do so promptly SATRA may exercise its rights under dauge 13.7. (c)
- 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.
- On termination of the Contract, however caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

#### PATENTS

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.

#### WARRANTY OF GOODS 15.

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.

#### DEFECTIVE GOODS

- 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
- SATRA is given a reasonable opportunity of examining such Goods, and 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.
- 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.
- 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.
- 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.
- 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 disuse 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 16.8 or 16.7 then the Client will be responsible for the payment of such costs.
- 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:
- 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
- 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
- the Client has breached any of the terms of the Contract under which the Goods were supplied; or 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;
- 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.
- SATRA shall not be obliged to take any step to attempt to obtain such recress 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
- nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional lisbility or obligations other than those referred to in condition 16.1.
- 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 dause 15.1.

Signed:

Terms and conditions - December 2018

Nam Viet Glove Joint Stock Company CHM0259430/1727/CL SATRA Reference: Date:

14<sup>th</sup> July 2017



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Customer details: Nam Viet Glove Joint Stock Company

23a Nguyen Huu Canh St

Ward 22

Binh Thanh District

**HCMC** Vietnam

For the attention of: Ooi Loon Seng

SATRA reference: SPC0257773 /172

Your reference:

3 June 2017 Date of report:

Samples received: 23 May 2017

Date(s) work

31 May to 3 June 2017

carried out:

# **TECHNICAL REPORT**

Subject: Testing of gloves identified as NPF-FT30-24LB in accordance with EN 420: 2003 + A1:

2009 clauses 5.1 Sizing and 5.2 Dexterity and EN 374-2: 2014

#### 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: Adam Mortiboys Position: PPE Technologist Safety Product Testing Department:

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## **Work Requested**

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 420:2003+A1:2009 clauses 5.1 length and fit and 5.2 dexterity and EN 374-2:2014.

Table 1 - Samples Received

Sample description stated by the cli-			
NPF-FT30-24L	B S-XL	Blue	Size: XL Weight: 3.8g



## Conclusion

Standard	00	Clause / Property	Result
EN 420: 2003 + A1:	5.1	Length and fit	See note ■
2009	5.2	Dexterity	Level 5
EN 974 0: 9944	7.2	Air leak	Pass
EN 374-2: 2014	7.3	Water leak	Pass

Note ■ – Where gloves do not meet the minimum length requirements specified in Table 1 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements.

Signed:

Adam martibays





## **Testing**

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity. Testing was carried out within the same environment.

## Requirements

Table 2 - Requirements for EN 420:2003 + A1:2009 Clause 5 Size and Dexterity

Glove size	6	7	8	9	10	11
Minimum length / mm	220	230	240	250	260	270

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 3 - Requirements for EN 374-2: 2014

7.2 Air leak test	No leak to be detected
7.3 Water leak test	No leak to be detected

adam martibay.





## **Test Results**

Table 4 - EN 420:2003 + A1:2009 Test Results for gloves identified as NPF-FT30-24LB

Clause / Test		Test Results	UoM	Result	
	Size	760	h /mm		
		Left	Right	1	
3 3 / 7	S	245	247		
1 1 / /	Con	nments on fit: Satisf	actory		
5 4 64 4 4	M	255	254		
5.1 Glove length, comfort and fit	Con	nments on fit: Satisf	actory	± 0.3 mm	See note
	L	254	253		
	100	ments on fit: Satisf			
	XL	245	244		
		ments on fit: Satisf		1000	
	Size	Minimum pin dia	ameter / mm		
	S	5.0			
5.2 Dexterity	M	5.0		N/A	Level 5
	L	5.0			
	XL	5.0			

Table 5 - EN 374-2:2014 Test Results of gloves identified as NPF-FT30-24LB

Clause / Test	101	est Results	UoM	Result
10- 110	Total Air Pressu	re Used 2.39 kPa	000	12.12
20, - 30	Sample size	Leaks	in The	ME
7.2 Air leak test	S	No leaks detected		Deve
	M	No leaks detected	± 2.8 mmH <sub>2</sub> 0	Pass
	011 L 0011	No leaks detected	00	m.
- 200	XL	No leaks detected	JUL WILL	11
The Wale	Sample size	Leaks	10,	10
10,0	S	No leaks detected	100	-
7.3 Water leak test	M	No leaks detected	N/A	Pass
10 . 5 . 50	CIL CL	No leaks detected	10/12 19	115
all I	XL	No leaks detected	10, 10	1

Signed:





#### TERMS AND CONDITIONS OF BUSINESS

#### GENERAL

Work done or services undertaken are subject to the terms and conditions detailed below and all other conditions, warranties and representations, expressed or implied are hereby excluded.

#### PRICES

Prices are based on current material and production costs, exchange rates, duty and freight and are subject to change without notice.

#### 3. DELIVERY ESTIMATES

Delivery estimates are made in good faith and date from receipt of a written order and full information to enable us to proceed. While SATRA or its subsidiaries (hereafter referred to as "SATRA") make every effort to fulfil them, such estimates are subject to unforeseen events and if not maintained, cannot give rise to any claim. Offers "ex stock" are subject to prior sale.

#### 4. CANCELLATION AND RETURNS

Cancellation of orders for goods, services, training or consultancy is only acceptable by prior agreement of SATRA and a charge will normally be made.

#### CLAIMS

Claims for errors, shortages etc should be notified within 10 days of date of receipt. In the event of goods damaged in transit, packing materials should be retained for examination; otherwise no liability can be accepted.

#### PAYMENT TERMS

Payment terms are net 21 days from date of invoice. Failure to comply with the terms of payment may result in delayed delivery of goods and services and a review of the Customer's credit account. Should the customer become subject to an administration order, or becomes bankrupt or goes into liquidation, SATRA has a right to cancel any contract and discontinue any work. SATRA reserves the right to adjust US Dollar and Euro sales price where customer exceeds credit terms and where the exchange rate has moved more than 10% since invoicing.

#### RETENTION OF TITLE

All goods remain the property of SATRA until paid in full. Under no circumstances will a customer's purchase order override SATRA's Retention of Title clause. In the case of software, the ownership of the software remains with SATRA. Payment of invoices in full will entitle the customer to use the software under licence until (a) they cease to be a member of SATRA or (b) they cease trading. In both instances, the licence shall then revert to SATRA.

#### GUARANTEE

All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.

#### TEST REPORTS

Results given in test reports refer only to samples submitted for analysis and tested by 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. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.

#### 10. TEST SAMPLES

Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.

#### RESPONSIBILITY

Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.

#### 12. CONFIDENTIALITY

Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:

- The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- iii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
- iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.

#### CONSTRUCTION AND ARBITRATION

The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009

Signed:

Adam martibays