



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

April 1, 2016

Viet Glove Corporation  
Mr. Terence Lim  
Quality Assurance & Regulatory Affairs Manager  
Cau Sat Hamlet, Lai Hung Commune  
Ben Cat District, Bau Bang Province  
VIETNAM

Re: K153562

Trade/Device Name: Powder Free Blue Nitrile Examination Glove  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: Class I  
Product Code: LZA  
Dated: February 23, 2016  
Received: March 4, 2016

Dear Mr. Terence Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please 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 yours,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Test Report No. 7191241593-EEC20/01-WBH**  
**dated 26 Aug 2020**



PSB Singapore

**Add value.  
Inspire trust.**

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

**SUBJECT:**

Testing of Examination Gloves submitted by VIET GLOVE CORPORATION  
on 03 Aug 2020.

**TESTED FOR:**

VIET GLOVE CORPORATION  
Land Lot No. 03, Map No. 37,  
Cau Sat Hamlet, Lai Hung Commune,  
Bau Bang District, Binh Duong Province,  
Vietnam.

**TEST DATE:**

04 Aug 2020 to 26 Aug 2020

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Size	Colour	Lot No.	Sample Received (pieces)	Manufacturer
1	Powder free exam nitrile gloves (non-sterile), 3.5gr	M	Blue	Nil	420	Viet Glove Corporation

Lot size as specified by client: 35,001 pcs to 150,000 pcs

**METHOD OF TEST:**

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

- Clauses 6.1.2 & 7.3 Freedom from Holes (Cross-reference to Test Method D5151)
- Clauses 6.1.3 & 7.4 Physical Dimensions Test
- Clauses 6.1.4 & 7.5 Physical Requirements Test – Die C, accelerated aging conducted according to Clause 7.5.2.1: temperature of  $70\pm 2^{\circ}\text{C}$  for  $166\pm 2\text{h}$  (Cross-reference to Test Method D412 and D573)
- Clauses 6.1.5 & 7.6 Powder-free Residue (Cross-reference to Test Method D6124)



Laboratory:  
TÜV SÜD PSB Pte. Ltd.  
No.1 Science Park Drive  
Singapore 118221

Phone : +65-6885 1333  
Fax : +65-6776 8670  
E-mail: enquiries@tuv-sud-psb.sg  
www.tuv-sud-psb.sg  
Co. Reg : 199002667R

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

**RESULTS:**

Sample: Powder free exam nitrile gloves (non-sterile), 3.5gr, Blue, Size M

**Table 1: Results for Freedom from Holes**

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
6.1.2 7.3	Freedom from holes	Shall not leak	10	200	0	Passed

**Table 2: Results for Physical Dimensions Test**

Clause	Tests	Requirements (mm)	Results (mm)			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.3 7.4	a) Width	For size M: 95 ± 10	97	98	99	1	13	0	Passed
	b) Length	For size M: ≥ 230	243	246	249				
	c) Finger thickness	≥ 0.05	0.10	0.11	0.11				
	d) Palm thickness	≥ 0.05	0.06	0.06	0.07				

**Table 3: Results for Physical Requirements Test – before accelerated aging**

Clause	Tests	Requirements	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 14	19	24	30	1	13	0	Passed
	Ultimate elongation (%)	≥ 500	537	571	597				

**Table 4: Results for Physical Requirements Test – after accelerated aging**

Clause	Tests	Requirements	Results			Number of pieces			Inferred results
			Min.	Mean	Max.	Non-compliers allowed	Tested	Actual non-compliers found	
6.1.4 7.5	Tensile strength (MPa)	≥ 14	20	24	26	1	13	0	Passed
	Ultimate elongation (%)	≥ 400	530	545	562				



**RESULTS (cont'd):**

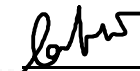
Sample: Powder free exam nitrile gloves (non-sterile), 3.5gr, Blue, Size M

Table 5: Results for Powder Free Gloves

Clause	Tests	Requirements	Result	Inferred Results
6.1.5 7.6	Powder-free gloves	Powder residue $\leq 2.0$ mg	0.21 mg per glove	Passed



Yeo Poh Kwang  
Associate Engineer



Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo: Powder free exam nitrile gloves (non-sterile), 3.5gr, Blue, Size M

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011



# EU Type-Examination Certificate

**Certificate number: 2777/11024-02/E00-00**

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

**Product reference: Description:**

9PFNBR Non-Sterile Powder Free Nitrile Disposable Glove. Available in blue, black, purple and white.

**Sizes:** 6 - 10**Classification:****EN ISO 374-1:2016 Type B**

Methanol (A)  
n-Heptane (J)  
40% Sodium Hydroxide (K)  
30% Hydrogen Peroxide (P)  
40% Hydrofluoric acid (S)  
37% Formaldehyde (T)

**Level**

0  
0  
6  
2  
0  
4

**EN 374-4:2013 Degradation %**

64.0  
40.9  
-18.8  
13.3  
Not done  
10.6

**EN ISO 374-5:2016**

Protection against bacteria and fungi  
Protection against viruses

**Level**

Pass  
Pass

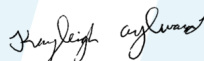
**Standards/Technical specifications applied:**

EN ISO 374-1:2016; EN 420: 2003+A1: 2009; EN ISO 374-5:2016

**Technical reports/Approval documents:**

SATRA: CHM0270625/1819/CLB, CHM0243924/1612/EN, SPC0244013/1612; CHM0253621/1703/CL/A; CHM0253621/1703/CL/B, CHM0265919/1801/EN/A, CHM0265919/1801/EN/B, SPC0266012/1801, CHM0272778/1827/LH, CHM0276386/1840/JH

Signed on behalf of SATRA:



Kayleigh Aylward



Geoff Graham

**Date first issued: 03/08/2018****Date of issue: 18/02/2019****Expiry date: 03/08/2023**

# TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.



# PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to:

*Viet Glove Corporation  
Cau Sat Hamlet  
Lai Hung Commune  
Binh Duong Province  
Vietnam*

This is to certify that the following products tested under SATRA reports referenced: STE0319865 & CHM0321319/2142/CC & SPC0321337/2142 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11024-02/E00-00	9PFNBR	Non-Sterile Powder Free Nitrile Disposable Glove Available in various colours	EN ISO 374-1:2016 Type B

Dated: 18<sup>th</sup> November 2021

This certificate is  
valid until:

*November 2022*

Signed By G Graham

For and on behalf of SATRA Technology  
Europe Limited

*The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.*

*SATRA Technology Europe Limited, Bracetown Business Park Clonree Dublin 15 D15 YN2P. Republic of Ireland.  
(Notified Body number 2777)*

*Tel: +353 (0) 1 437 2484 Web: [www.satraeurope.com](http://www.satraeurope.com)*

Customer details: SATRA Technology Europe Ltd  
Bracetown Business Park  
Clonee  
County Meath  
Dublin 15  
Eire

SATRA reference: CHM0321319/2142/C  
Your reference: STE0319865  
Date of report: 10<sup>th</sup> November 2021  
Samples received: 22<sup>nd</sup> October 2021  
Date(s) work carried out: 2<sup>nd</sup> November 2021 to 10<sup>th</sup> November 2021

## TECHNICAL REPORT

SATRA Technology Europe Ltd: Certificate Number: 2777/11024-02/E00-00

Customer: Viet Glove Corporation  
Cau Sat Hamlet  
Lai Hung Commune  
Binh Duong Province  
Vietnam

Subject: Regulation 2016/425 Module C2 testing of gloves described as 9PFNBR Non sterile powder free nitrile disposable glove in accordance with EN 16523-1:2015+A1:2018 resistance to permeation by chemicals against 40% Sodium hydroxide 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 opinions and interpretations of results, 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.

Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor  $k=2$ , which provides a coverage probability of approximately 95%.

When reporting results against a conformance statement (Pass/Fail or the allocation of a class or level) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.

Where the result corrected for uncertainty falls within the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 2.5% and SATRA will in this instance quote a Pass/Fail, class or level.

Where the result corrected for uncertainty falls outside of the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 50%. In this instance SATRA will not provide a Pass/Fail statement or a class or level but will include information in the notes in relation to the result obtained.

Please note that where uncertainty of measurement values have not been included then uncertainty has not been applied to these results. SATRA uncertainty of measurement values are however available upon request.

Report signed by: Chelsea Craig  
Position: Technical Administrator  
Department: Chemical & Analytical Technology





## WORK REQUESTED:

Samples of gloves described as 9PFNBR Non sterile powder free nitrile disposable glove were obtained by SATRA Technology Europe Ltd from Sang Viet Co Ltd on the 15<sup>th</sup> October 2021 in glove size S, colour Blue (note – product marked as 029-15). The gloves were received by SATRA Technology UK on the 22<sup>nd</sup> October 2021 for testing in accordance with EN 16523-1:2015+A1:2018 and with the performance requirements of EN ISO 374-1:2016+A1:2018 to demonstrate ongoing production compliance with Module C2 of Regulation (EU) 2016/425. These gloves are certified by certificate number 2777/11024-02/E00-00.

## SAMPLES SUBMITTED:



Samples described as 9PFNBR Non sterile powder free nitrile disposable glove

## CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as 9PFNBR Non sterile powder free nitrile disposable glove achieved the following performance levels:

Chemical	Performance level
37% Formaldehyde (CAS: 50-00-0)	5
40% Sodium hydroxide (CAS: 1310-73-2)	6
Mean thickness of 20 specimens prepared from the palm area of the gloves (mm)	0.06

Full results are reported in the following tables.

**TESTING REQUIRED:**

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
- Indicative thickness measurements of 20 specimens prepared from the palm area of the gloves

**RESULTS AND REQUIREMENTS:**

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

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

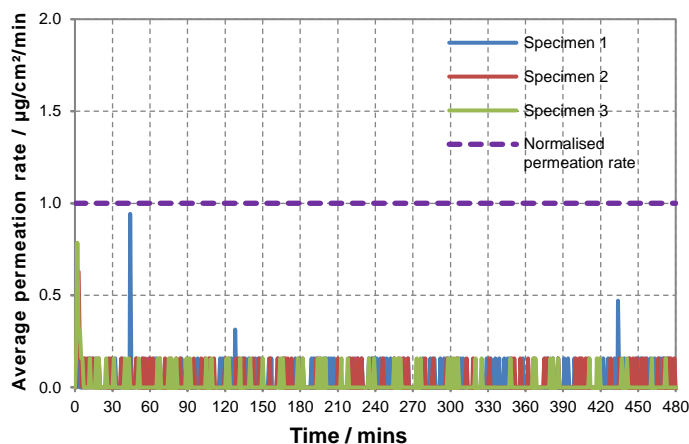
Performance levels are based on the lowest individual result achieved per chemical.



Test/Property	Sample reference:	9PFNBR Non sterile powder free nitrile disposable glove		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009  Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium Hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)△	Breakthrough time (mins)	
	1	0.09	>480	
	2	0.07	>480	
	3	0.08	>480	
	Test result:	>480		
	UoM:	<1		
Visual appearance of specimens after testing:		No change		

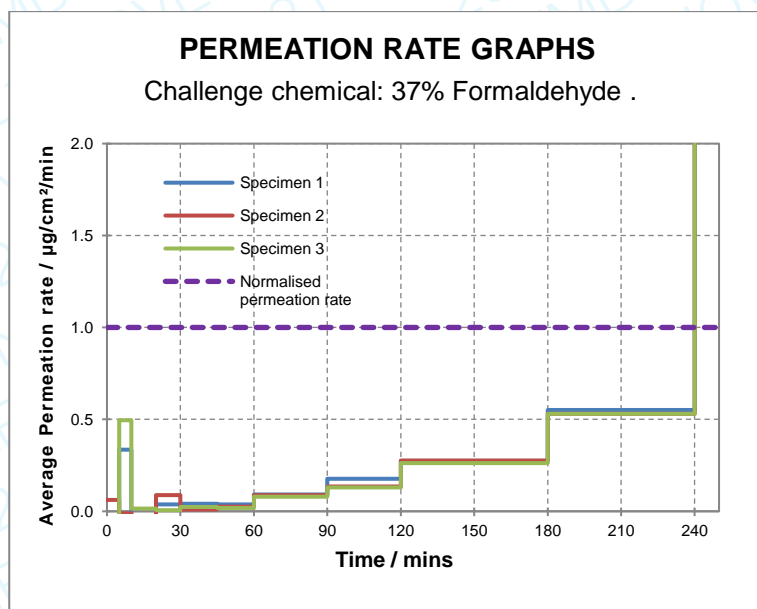
## PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide.




Test/Property	Sample reference:	9PFNBR Non sterile powder free nitrile disposable glove		Performance		
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025  Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 5		
		Normalised permeation rate (NPR): 1 µg/cm²/min				
		Detection technique: HPLC-DAD (periodic measurement)				
		Collection medium: Deionised water (closed loop)				
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)				
		Test temperature: (23 ± 1) °C				
	Specimen	Thickness (mm)△	Breakthrough time (mins)▼			
		1	0.06			Between 241 to 360
		2	0.06			Between 241 to 360
		3	0.09			Between 241 to 360
			Test result:			Between 241 to 360
		UoM:	See below			
Visual appearance of specimens after testing:		Swollen and discoloured				

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



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

- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

Indicative thickness measurements of 20 specimens prepared from the palm area of the gloves

Thickness measurement (mm)			
1	0.06	11	0.07
2	0.06	12	0.05
3	0.08	13	0.07
4	0.05	14	0.07
5	0.07	15	0.07
6	0.07	16	0.08
7	0.06	17	0.06
8	0.06	18	0.06
9	0.07	19	0.07
10	0.06	20	0.05
Mean thickness (mm)		0.06	



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

### 1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
  - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
  - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
  - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

### 2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

### 3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all proprietary rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### 4. SUSPENSION OR TERMINATION OF SERVICES

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

### 5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
  - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
  - (b) fraud or fraudulent misrepresentation;
  - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
  - (d) defective products under the Consumer Protection Act 1987; or
  - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

### 6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

### 7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

### 8. AMENDMENT

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

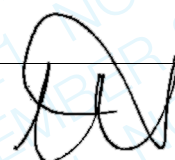
### 9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereto, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

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

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents; or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2021





Customer details: SATRA Technology Europe Ltd  
Bracetown Business Park  
Clonee  
County Meath  
Dublin 15  
Eire

SATRA reference: SPC0321337 /2142

STE/CHT Job No.: STE0319865

Date of report: 15 November 2021

Samples received: 22 October 2021

Date(s) work carried out: 9 November 2021

## TECHNICAL REPORT

SATRA Technology Europe Ltd

Certificate Number: 2777/11024-02/E00-00

Customer: Viet Glove Corporation

Cau Sat Hamlet  
Lai Hung Commune  
Binh Duong Province  
Vietnam

Subject: Regulation 2016/425 Module C2 testing of glove style identified as 9PFNBRL Non sterile powder free nitrile disposable glove in accordance with EN ISO 374-5:2016 for water leak (viral). 20 water leaks - deviation from standard

### 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 opinions and interpretations of results, 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.

Where values for uncertainty of measurement are included within the report then the uncertainty of the corresponding results are based on a standard uncertainty multiplied by a coverage factor  $k=2$ , which provides a coverage probability of approximately 95%.

When reporting results against a conformance statement (Pass/Fail or the allocation of a class or level) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.

Where the result corrected for uncertainty falls within the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 2.5% and SATRA will in this instance quote a Pass/Fail, class or level.

Where the result corrected for uncertainty falls outside of the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 50%. In this instance SATRA will not provide a Pass/Fail statement or a class or level but will include information in the notes in relation to the result obtained.

Please note that where uncertainty of measurement values have not been included then uncertainty has not been applied to these results. SATRA uncertainty of measurement values are however available upon request.

Report signed by: Debbie Reed  
Position: PPE Technologist  
Department: Safety Product Testing



## Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN ISO 374-2: 2019 clause 7.3 Water leak to demonstrate ongoing compliance with Regulation 2016/425 module C2. The gloves were obtained from Sang Viet Co Ltd

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
9PFNBRRNon sterile powder free nitrile disposable glove ( Product code 029-15)	Small	Blue	Size: S (7) Weight: 3.9g



## Conclusion

Standard	Clause / Property	Result
EN ISO 374-2: 2019	7.3 Water leak	Pass

## Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at  $(23 \pm 2) ^\circ\text{C}$  and  $(50 \pm 5) \%$  relative humidity. Testing was carried out within the same environment.

## Requirements

Table 2 - Requirements for EN ISO 374-2: 2019

7.3 Water leak test	No leak to be detected
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## Test Results

Table 3 – EN ISO 374-2:2019 Test Results of gloves identified as 9PFNBRNon sterile powder free nitrile disposable glove

Clause / Test	Test Results		UoM	Result
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		
	S	No leak detected		



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

### 1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
  - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
  - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
  - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

### 2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

### 3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all proprietary rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### 4. SUSPENSION OR TERMINATION OF SERVICES

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

### 5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
  - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
  - (b) fraud or fraudulent misrepresentation;
  - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
  - (d) defective products under the Consumer Protection Act 1987; or
  - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

### 6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

### 7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

### 8. AMENDMENT

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

### 9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

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

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2021

Nombre del producto	Guantes de examen de nitrilo sin polvo		
Tipo	Guantes de examen de nitrilo, libre de látex, sin polvo ,no estériles, de un sólo uso		
Diseño y características	Ambidiestro, dedos rectos, con textura de dedos, manguito de cuentas		
Color	Azul		
Peso medio de tamaño mediano	4,0 gm (± 0,2 gm)		
Material	Nitrilo (acrilonitrilo butadieno carboxilado)		
Uso	Para ser usado en exámenes médicos, procedimientos diagnósticos y terapéuticos con el fin de proteger al personal clínico y paciente de contaminación cruzada o infección.		
Condición de almacenamiento	Los guantes mantendrán sus propiedades cuando se almacenen en estado seco. Evite la luz solar directa		
Vida útil	Los guantes tendrán una vida útil de 5 años a partir de la fecha de fabricación siempre que se mantengan las condiciones de almacenamiento.		
Característica del producto:			
Dimensión	Tamaño	Ancho de la palma (mm)	Longitud (mm)
	Pequeño	85 ± 5mm	230min
	Medio	95 ± 5mm	230min
	Grande	105 ± 5mm	230min
Espesor	Espesor de pared única (mm)		
	Puño	0,07 ± 0,02	
	Palma	0,08 ± 0,02	
	Dedo	0,09 ± 0,02	
Propiedades físicas		Sin envejecer	Envejecido
	Resistencia a la tracción (Mpa)	14 mín.	14 mín.
	Alargamiento definitivo (%)	500 minutos	400 minutos
Polvo residual	2,0 mg/guante máximo		
Proteína total	no presente		
Peso (gr)	Pequeño	3,7 ± 0,2	
	Medio	4.0 ± 0.2	
	Grande	4.3 ± 0.2	
Especificación de calidad			
Especificación de calidad *Y - Aceptar sin defectos *n - número de muestras		Estándar interno	Norma ASTM 6319-10
	Criterios de inspección	Plan de muestreo / AQL	Plan de muestreo / AQL
	Dimensión	S2 - AQL 4.0	S2 - AQL 4.0
	Propiedades físicas	S2 - AQL 4.0	S2 - AQL 4.0
	Prueba hermética	G1 - AQL 2.5	G1 - AQL 2.5
	Inpección Visual- Mayor	G1- AQL 2.5	G1 - AQL 2.5
	Inpección visual- Menor	G1- AQL 4.0	G1 - AQL 4.0
	Polvo residual	n = 5 (Y)	n = 5 (Y)
	Etiquetado de envases	n = 6 (Y)	-
	Conteo físico de guantes	S2 - AQL 4.0	-
Configuración y etiquetado de envases:			
Embalaje	100/200 guantes por dispensador interior (por peso) 10/20 Dispensadores por caja exterior		
Marcado de tamaño	El tamaño de los guantes está identificado en el dispensador y caja exterior		
Certificaciones			
EN ISO 374-2: 201	Para riesgo biológico		
EN ISO 374-1:2016+A1:2018	Para riesgo químico		
EN ISO 374-5:2016	Para evitar riesgos con virus		
ASTM D6319-19	Para guantes grado médico libres de polvo		





Departamento ANDID

MCL/MGR/CRS/Lps  
Ref. N° 2.655/21

CONCEDE A BIOSEGURIDAD CHILE LTDA., N° DE INSCRIPCIÓN EDM 549/21, COMO ESTABLECIMIENTO IMPORTADOR Y DISTRIBUIDOR DE DISPOSITIVOS MÉDICOS.

RESOLUCIÓN EXENTA N° \_\_\_\_\_/

SANTIAGO,

1865 29.04.2021

**VISTO ESTOS ANTECEDENTES:** El Formulario ANDID/004 de Solicitud de Inscripción de Empresa Importadora y Distribuidora de Dispositivos Médicos y los antecedentes presentados por Bioseguridad Chile Ltda.;

**TENIENDO PRESENTE:** las facultades que confiere el Decreto Ley N° 2.763 de 1979, el Decreto Supremo N° 1.222 de 1996, todos del Ministerio de Salud, y en uso de las facultades delegadas por la Resolución Exenta N° 191 de 5 de febrero de 2021, del Instituto de Salud Pública de Chile, dicto la siguiente:

### R E S O L U C I Ó N

**INSCRÍBASE** bajo el Número **EDM 549/21**, en el Sistema Nacional de Establecimientos como **IMPORTADOR Y DISTRIBUIDOR de dispositivos médicos**, a la persona natural o jurídica que a continuación se indica:

Nombre Razón Social : BIOSEGURIDAD CHILE LTDA.  
Nombre de Fantasía : BSC.  
RUT : 76.066.561-4.  
Representante Legal : RICARDO ANDRÉS ANDAUR SÁEZ.  
Dirección : AV. SANTA ISABEL 1292, PROVIDENCIA, SANTIAGO.

El presente documento no constituye una autorización del establecimiento ni registro sanitario de sus productos en el Instituto de Salud Pública de Chile. La calidad, seguridad y efectividad de los dispositivos médicos que la empresa comercializa, es de exclusiva responsabilidad del fabricante legal, importador y distribuidor.

Agótese y Comuníquese  
  
JEFE DR. JANEPSY DÍAZ TITO  
JEFA DEPARTAMENTO  
AGENCIA NACIONAL DE DISPOSITIVOS MÉDICOS, INNOVACIÓN Y DESARROLLO  
INSTITUTO DE SALUD PÚBLICA DE CHILE

Distribución:

- Interesado
  - Gestión de Trámites (2)
- (28/04/20- ANDID 63/21)

  
Trátese en el  
MINISTERIO DE FE  
Ministro de Fe  
Sharon Becerra Calderón

# Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM – BSI HACCP & GMP

This is to certify that:

**VIET GLOVE CORPORATION**

No.37, Cau Sat Hamlet,  
Lai Hung Commune,  
Bau Bang District,  
Binh Duong Province,  
Vietnam

Holds Certificate Number:

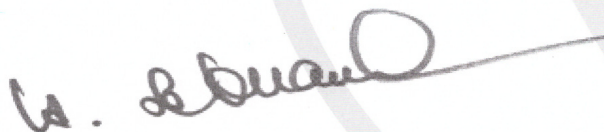
**HACCP 730307**

and operates a food safety management system that complies with the requirements of Codex Alimentarius Alinorm: 2003/13A (HACCP) and Good Manufacturing Practice (GMP) for the accompanying scope:

**The manufacture of:**

**Non-sterile, powder free nitrile examination gloves for food industry;**

**Non-sterile powder, powder free natural latex examination gloves (only labelling and packaging) for food industry.**



For and on behalf of BSI:

Le Duyen Anh, Managing Director Vietnam

Original Registration Date: **29/05/2020**

Effective Date: **29/05/2020**

Latest Revision Date: **29/05/2020**

Expiry Date: **28/05/2023**

Page: 1 of 1

...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

This certificate can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory).

Further clarifications regarding the scope of this certificate and the applicability of BSI HACCP & GMP requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

BSI Vietnam Headquarters: Suite 1106, 11<sup>th</sup> Floor, Citilight Tower, 45 Vo Thi Sau Street, Dakao Ward, District 1, HCMC, Vietnam. Telephone: +84 (28) 3820 0066.  
A member of the BSI Group of Companies.



# Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ AN TOÀN THỰC PHẨM – BSI HACCP & GMP

Xác nhận rằng:

**CÔNG TY CỔ PHẦN GĂNG VIỆT**

Số 37, Ấp Cầu Sắt,  
Xã Lai Hưng,  
Huyện Bàu Bàng,  
Tỉnh Bình Dương,  
Việt Nam

Giữ giấy chứng nhận số:

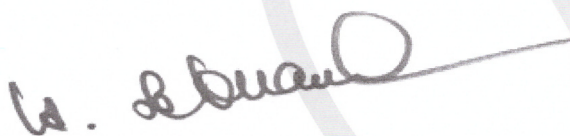
**HACCP 730307**

và vận hành hệ thống quản lý An Toàn Thực Phẩm tuân thủ các yêu cầu của Codex Alimentarius Alinorm: 2003/13A (HACCP) và Thực Hành Sản Xuất Tốt (GMP) cho phạm vi:

**Sản xuất:**

**Găng tay y tế nitrile không tiết trùng, không bột cho ngành công nghiệp thực phẩm.**

**Găng tay cao su thiên nhiên y tế không tiết trùng có bột và không bột (chỉ dán nhãn và đóng gói) cho ngành công nghiệp thực phẩm.**



Đại diện cho tập đoàn BSI:

*Tổng Giám đốc BSI Việt Nam, Ông Lê Duyên Anh*

Ngày đăng ký đầu tiên: **29/05/2020**

Ngày sửa đổi sau cùng: **29/05/2020**

Ngày hiệu lực: **29/05/2020**

Ngày hết hiệu lực: **28/05/2023**

Trang 1/1

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BSI Vietnam Headquarters: Suite 1106, 11<sup>th</sup> Floor, Citilight Tower, 45 Vo Thi Sau Street, Dakao Ward, District 1, HCMC, Vietnam. Telephone: +84 (28) 3820 0066. A member of the BSI Group of Companies.

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

VIET GLOVE CORPORATION  
No. 37, Cau Sat Hamlet,  
Lai Hung Commune,  
Bau Bang District,  
Binh Duong Province,  
590000  
Vietnam

Holds Certificate Number:

**FM 644239**

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

The manufacture and distribution of:  
Non-sterile powder free nitrile examination gloves  
Non-sterile powder free, powdered natural rubber latex examination gloves (only labelling and packaging).

For and on behalf of BSI:



Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2016-01-27

Latest Revision Date: 2021-12-16

Effective Date: 2022-01-27

Expiry Date: 2025-01-26

Page: 1 of 1



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# Certificate of Registration

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

This is to certify that:

VIET GLOVE CORPORATION  
No.37, Cau Sat Hamlet,  
Lai Hung Commune,  
Bau Bang District,  
Binh Duong Province,  
590000  
Vietnam

Holds Certificate Number:

**MD 644242**

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

The manufacture and distribution of:

Non - sterile powder, powder free nitrile examination gloves;

Non - sterile powder, powder free natural latex examination gloves (only labelling and packaging).



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-01-26

Latest Revision Date: 2021-12-30

Effective Date: 2022-01-26

Expiry Date: 2025-01-25

Page: 1 of 1



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
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Certificado CL21/819943354

SGS

El sistema de gestión de

# BIOSEGURIDAD CHILE LIMITADA

Crescente Errazuriz 1785, Ñuñoa, Santiago, Región Metropolitana, Chile

ha sido evaluado y certificado que cumple con los requisitos de

**ISO 9001:2015**

Para las siguientes actividades

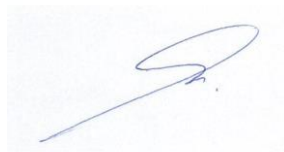
Servicios de Laboratorio que incluye el transporte de muestras biológicas hacia laboratorios, y la trazabilidad en el transporte de dichas muestras biológicas.

Este certificado es válido desde 24 de Octubre de 2022 hasta 20 de Octubre de 2024 y su validez está sujeta al resultado satisfactorio de las auditorías de seguimiento.

Registro Nro. SC 002

Registro Nacional Nro. 12682

Edición 2. Certificada desde 21 de octubre de 2021



Autorizado por  
Mario Ferrari

SGS Certificación SpA.  
Puerto Madero 130, Pudahuel, Santiago, Chile  
t + 56 228989500 - [www.sgs.com](http://www.sgs.com)



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