

SMART GLOVE HOLDINGS SDN BHD (430860-X)

Date: 07 August 2020

Confidential
Restricted circulation

To: **Business Partners & Governmental Bodies**

SMART GLOVE GROUP OF COMPANIES

We are pleased to inform that Smart Glove Holdings Sdn Bhd ("SGH") is a company incorporated under the laws of Malaysia, with its business address at Lot 6487 Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang, Malaysia. SGH wholly owns (100%) several glove manufacturing companies in Malaysia and Indonesia, and together with a Singapore-based international supply chain, sales and marketing company, we are referred to as the "**Smart Glove Group of Companies**".

Details of the companies under the Smart Glove Group are as follows:-

Company Name	Address	D&B no.
Smart Glove Corporation Sdn. Bhd.	Lot 6487 Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang Malaysia	652766320
GX Corporation Sdn Bhd	Lot 6491, Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang Malaysia	894327329
Platinum Glove Industries Sdn Bhd	Lot 6491-A, Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang Malaysia	865770747
Sigma Glove Industries Sdn Bhd	Lot 6497, Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang Malaysia	865784987
PT Smart Glove Indonesia	Jl. Pelita Raya No.5-7, KIM Star, Tanjong Morawa, 20362 Sumatera, Indonesia	726584902
Smart Glove International Pte Ltd	No. 2, Kallang Ave #07-05, CT Hub, Singapore, 339407	659506974

The Group structure is appended at the end of this letter.

All the companies under the Smart Glove Group are managed by the common management team in SGH and all the factories adopt and implement common Policies and Standard Operating Procedures.

Lot 6487, Batu 5 ¾ Sementa, Jalan Kapar, 42100 Klang, Selangor.
TEL: 03-32916100/7100 FAX: 03-32917526 (www.smartglove.com.my)



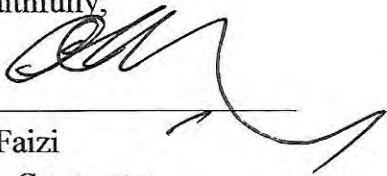
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In the premise, documentations such as product certification, material data sheet, etc. issued to any one of the companies under Smart Glove Group is applicable and valid to be relied upon for the purpose of the product produced and supplied by the other companies listed above.

This declaration letter is issued to confirm the relationship of the companies under the Smart Glove Group as requested by its Business Partners for the purposes of tender evaluation or similar purposes and is not for any other purposes. This letter should not be circulated to other parties without prior consent of Smart Glove Group.

Please contact the undersigned should recipient of this declaration letter require any further clarification or information.

Yours faithfully,



Ahmad Faizi
Director, Corporate
Group Corporate & Legal Department
Smart Glove Group

SMART GLOVE GROUP ORGANIZATION STRUCTURE



EU Type-Examination Certificate

Certificate number: 2777/12322-02/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:

3mil powder free nitrile examination gloves

Description:

Five fingered blue powder free nitrile examination gloves.

4mil powder free nitrile examination gloves

Five fingered blue powder free nitrile examination gloves.

Sizes: 6 -11**Classification:****EN ISO 374-1: 2016 /Type C**

Acetone (B)
Diethylamine (G)
Ethyl acetate (I)
n-heptane (J)
40% Sodium hydroxide (K)
96% Sulphuric acid (L)

Level	EN ISO 374-4:2013	% Degradation
0		100
0		92.3
0		87.7
1		43
6		3.5
0		100

EN ISO 374-5: 2016

Protection against Bacteria and fungi
Protection against viruses

Level
Pass
Pass

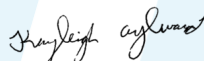
Standards/Technical specifications applied:

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

Technical reports/Approval documents:

SATRA: PRC0253480/1702/SPT, PRC0253480/1702/EN/A, PRC0253480/1702/EN/B, PRC0253480/1702/EN/D, PRC0253480/1702/EN/E, PRC0253480/1702/EN/G, PRC0253480/1702/EN/I, CHM0282156/1910/JG

Signed on behalf of SATRA:



Kayleigh Aylward



Quincey Brown

Date first issued: 12/03/2019

Date of issue: 14/06/2019

Expiry date: 12/03/2024

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:

GX Corporation (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan
5 3/4 Milestone
Sementa, Jalan Kapar
Klang
Selangor Darul Ehsan
Malaysia
42100

This is to certify that the following products tested under SATRA reports referenced: STE0301487 & CHM0303837/2043/LC & SPC0303806/2043 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
2777/12322-02/E00-00	3mil/4mil powder free nitrile examination glove	Blue powder free nitrile examination glove	EN ISO 374-1:2016 Type C & EN ISO 374-5:2016

Dated: 10th November 2020

This certificate is
valid until:

November 2021

Signed By (Alan Weston)

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

Customer details: GX Corporation (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan
5 3/4 Milestone
Sementa, Jalan Kapar
Klang
Selangor Darul Ehsan
Malaysia
42100

SATRA reference: PRC0253480/1702/EN
/A

Your reference:

Date of report: 6th March 2017

Samples received: 12th January 2017

For the attention of: Zatee

Date(s) work carried out: 31st January to 3rd March 2017

TECHNICAL REPORT

Subject: Chemical innocuousness testing in accordance with BS EN 420: 2003 + A1: 2009 and BS EN 16523: 2015 resistance to permeation by chemicals on gloves described as 3mil p/f nitrile examination gloves against acetone, ethyl acetate, n-heptane and 96% sulphuric acid.

Conditions of Issue:

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

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

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

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

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

Report signed by: Emma Norris
Position: Chemical Technologist
Department: Chemica & Analytical Technology

WORK REQUESTED:

Samples of gloves described as 3mil p/f nitrile examination gloves were received on the 12th January 2017 for testing in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and BS EN 16523-1:2015 and assessment in accordance with the requirements of BS EN ISO 374-1:2016.

CONCLUSION:

The samples of gloves described as 3mil p/f nitrile examination gloves were assessed in accordance with the innocuousness requirements of BS EN 420:2003 + A1:2009 and were found to meet with the requirement for pH value and the REACH annex XVII requirement for PAHs. When assessed in accordance with the requirements of BS EN ISO 374-1:2016 the samples of gloves described as 3mil p/f nitrile examination gloves achieved the following performance levels:

Chemical	Performance level
Acetone (CAS: 67-64-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Ethyl acetate (CAS: 141-78-6)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
n-Heptane (CAS: 142-82-5)	1
96% Sulphuric acid (CAS: 7664-93-9)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved

Full results are given in the following tables.

TESTING REQUIRED:

- BS EN 420:2003 + A1: 2009 Clause 4.3.2 pH Value (ISO 3071 for textiles & other materials & ISO 4045 for leathers)
- #SATRA SOP CAT-018 – Determination of PAHs (based on ZEK 01.4-08)
- BS EN 16523-1:2015 - Determination of material resistance to permeation by chemicals. Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

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

Date of determination: 3rd February 2017

Sample	Method	pH Value	UoM	Pass/Fail
3mil p/f nitrile examination gloves	ISO 3071: 2005 (water extraction)	7.1	± 0.1	Pass
Requirement	pH value greater than 3.5 and less than 9.5			

The extraction solution temperature was 20°C and at pH 7.3

≠SATRA SOP CAT-018 – Determination of PAHs

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

Sample	PAHs detected (mg/kg)	Pass/Fail
3mil p/f nitrile examination gloves	<0.2 (of each PAH listed in the appendices)	Pass
Requirements: REACH 1907/2006 annex XVII entry number 50	<1mg/kg of each PAH listed in the appendices	-

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

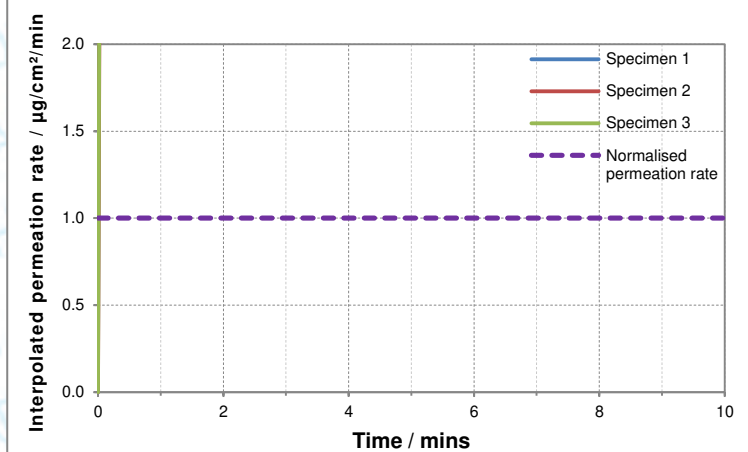
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

Test/Property	Sample reference:	3mil p/f nitrile examination gloves		Performance
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-005 Using brass alloy permeation cells with standardised dimensions	Test information:	Chemical: Acetone		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)Δ	Breakthrough time (mins)^	
	1	0.06	<1	
	2	0.06	<1	
	3	0.06	<1	
	Test result:	<1		
	UoM:	<1		
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

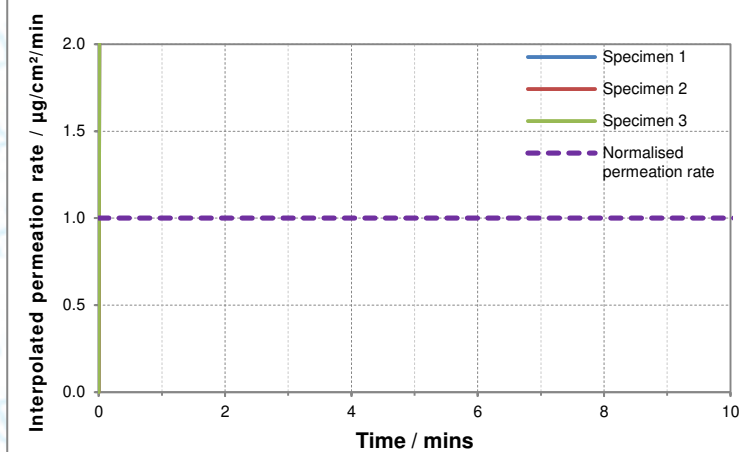
Challenge chemical: Acetone



Test/Property	Sample reference:	3mil p/f nitrile examination gloves		Performance
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-005 Using brass alloy permeation cells with standardised dimensions	Test information:	Chemical: Ethyl acetate		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm) ^Δ	Breakthrough time (mins) [▲]	
	1	0.06	<1	
	2	0.06	<1	
	3	0.06	<1	
	Test result:	<1		
	UoM:	<1		
Visual appearance of specimens after testing:		No change		

PERMEATION RATE GRAPHS

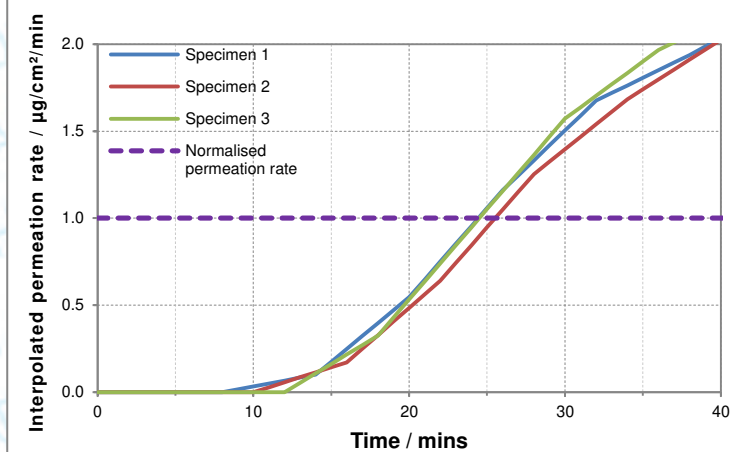
Challenge chemical: Ethyl acetate



Test/Property	Sample reference:	3mil p/f nitrile examination gloves		Performance
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-005 Using brass alloy permeation cells with standardised dimensions	Test information:	Chemical: n-heptane		Level 1
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique: GC-FID (periodic measurement)		
		Collection medium: Dry air (open loop)		
		Collection medium flow rate: 335 – 380 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm) ^Δ	Breakthrough time (mins) [▲]	
	1	0.06	24	
	2	0.06	25	
	3	0.06	24	
	Test result:	24		
	UoM:	1		
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

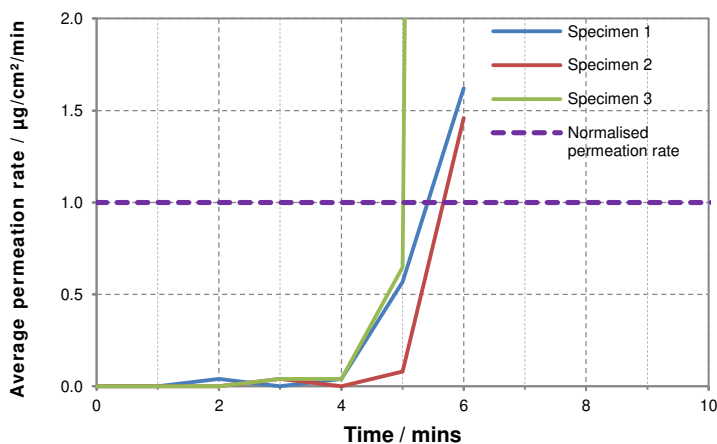
Challenge chemical: n-heptane



Test/Property	Sample reference:	3mil p/f nitrile examination gloves		Performance
BS EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 96% sulphuric acid		The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
		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		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)	
	1	0.06	5	
	2	0.07	6	
	3	0.07	6	
		Test result:	5	
		UoM:	<1	
Visual appearance of specimens after testing:		Discoloured and degraded		

PERMEATION RATE GRAPHS

Challenge chemical: 96% sulphuric acid



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

▲ The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results ≤ 60 minutes as specified in table 1 of BS EN 16523-1:2015 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.

APPENDICES:

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

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



Gloves described as 3mil p/f nitrile examination gloves

TERMS AND CONDITIONS OF BUSINESS

1. **GENERAL**
Work done or services undertaken are subject to the terms and conditions detailed below and all other conditions, warranties and representations, expressed or implied are hereby excluded.
2. **PRICES**
Prices are based on current material and production costs, exchange rates, duty and freight and are subject to change without notice.
3. **DELIVERY ESTIMATES**
Delivery estimates are made in good faith and date from receipt of a written order and full information to enable us to proceed. While SATRA or its subsidiaries (hereafter referred to as "SATRA") make every effort to fulfil them, such estimates are subject to unforeseen events and if not maintained, cannot give rise to any claim. Offers "ex stock" are subject to prior sale.
4. **CANCELLATION AND RETURNS**
Cancellation of orders for goods, services, training or consultancy is only acceptable by prior agreement of SATRA and a charge will normally be made.
5. **CLAIMS**
Claims for errors, shortages etc should be notified within 10 days of date of receipt. In the event of goods damaged in transit, packing materials should be retained for examination; otherwise no liability can be accepted.
6. **PAYMENT TERMS**
Payment terms are net 21 days from date of invoice. Failure to comply with the terms of payment may result in delayed delivery of goods and services and a review of the Customer's credit account. Should the customer become subject to an administration order, or becomes bankrupt or goes into liquidation, SATRA has a right to cancel any contract and discontinue any work. SATRA reserves the right to adjust US Dollar and Euro sales price where customer exceeds credit terms and where the exchange rate has moved more than 10% since invoicing.
7. **RETENTION OF TITLE**
All goods remain the property of SATRA until paid in full. Under no circumstances will a customer's purchase order override SATRA's Retention of Title clause. In the case of software, the ownership of the software remains with SATRA. Payment of invoices in full will entitle the customer to use the software under licence until (a) they cease to be a member of SATRA or (b) they cease trading. In both instances, the licence shall then revert to SATRA.
8. **GUARANTEE**
All goods manufactured by SATRA are guaranteed both as regards material and workmanship. Any part returned carriage paid, within twelve months from date of supply and found defective, will be repaired or replaced at SATRA's option free of charge. SATRA admits no liability for loss, damage or delay consequent on any defect in any goods supplied by SATRA.
9. **TEST REPORTS**
Results given in test reports refer only to samples submitted for analysis and tested by SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the Customer as a result of information supplied in a test report.
10. **TEST SAMPLES**
Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.
11. **RESPONSIBILITY**
Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.
12. **CONFIDENTIALITY**
Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:
 - i. The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
 - ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
 - iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.
13. **CONSTRUCTION AND ARBITRATION**
The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009

Customer details: GX Corporation (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan
5 3/4 Milestone
Sementa, Jalan Kapar
Klang
Selangor Darul Ehsan
Malaysia
42100

SATRA reference: PRC0253480/1702/EN
/I

Your reference:

Date of report: 23rd March 2017

Samples received: 12th January 2017

For the attention of: Zatee

Date(s) work carried out: 15th to 16th March 2017

TECHNICAL REPORT

Subject: BS EN 374-4: 2013 determination of resistance to degradation by chemicals on gloves described as 3mil p/f nitrile examination gloves against diethylamine and 40% sodium hydroxide.

Conditions of Issue:

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

Report signed by: Emma Norris
Position: Chemical Technologist
Department: Chemical & Analytical Technology

WORK REQUESTED:

Samples of gloves described as 3mil p/f nitrile examination gloves were received on the 12th January 2017 for testing in accordance with BS EN 374-4:2013. Full results are given below.

CONCLUSION:

When assessed in accordance with BS EN 374-4:2013 the samples of gloves described as 3mil p/f nitrile examination gloves achieved the following degradation results:

Chemical	Mean degradation / %
Diethylamine (CAS: 109-89-7)	92.3
40% Sodium hydroxide (CAS: 1310-73-2)	3.5

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

TESTING REQUIRED:

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

RESULTS:

Sample description:	3mil p/f nitrile examination gloves		
Challenge chemical:	Diethylamine (CAS: 109-89-7)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	92.6	90.4	94.1
Mean degradation (DR) / %:	92.3		
Standard deviation (σ_{DR}) / %:	1.9		
UoM ♦ / ± %:	14.0		
Appearance of samples after testing:	Swollen and softened		

Sample description:	3mil p/f nitrile examination gloves		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	7.5	13.8	-10.8
Mean degradation (DR) / %:	3.5		
Standard deviation (σ_{DR}) / %:	12.8		
UoM ♦ / ± %:	27.8		
Appearance of samples after testing:	No change		

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

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

APPENDICES:



Gloves described as 3mil p/f nitrile examination gloves

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Unless otherwise agreed in advance, test samples will be disposed of 6 weeks after the date of the final report. If required, samples can be returned at the Customer's expense.
11. **RESPONSIBILITY**
Every effort is made to ensure accuracy in description, drawings and other information in correspondence, catalogues, etc but no warranty is given in this respect and SATRA shall not be liable for any error therein. SATRA carries out all tests and/or advises only on the basis that the same are carried out, made or given without any responsibility whether for negligence or otherwise. SATRA and its servants or agents will not be liable for any damage or loss direct or indirect of whatsoever kind, whether or not the same results directly or indirectly from negligence on the part of SATRA or its servants or agents.
12. **CONFIDENTIALITY**
Unless specifically excluded in the terms of an individual contract between SATRA and its Customer, the following shall apply to all reports, advice, drawings, photographs, specifications or data:
 - i. The above shall not be disclosed to third parties or used in litigation without the consent of SATRA.
 - ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
 - iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.
13. **CONSTRUCTION AND ARBITRATION**
The laws of England shall govern all contracts and the parties submit to exclusive jurisdiction of the courts of England, unless otherwise agreed.

Issue Date: 1st October 2009



SATRA Technology Centre Ltd
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Customer details: GX Corporation (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan
5 3/4 Milestone
Sementa, Jalan Kapar
Klang
Selangor Darul Ehsan
Malaysia
42100

SATRA reference: CHM0282156/1910/JG

Your reference:

Date of report: 23rd April 2019

Samples received: 18th March 2019

Date(s) work carried out: 15th to 18th April 2019

TECHNICAL REPORT

Subject: Testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens on gloves described as 3mil Powder Free Nitrile Examination Glove.

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.

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.

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Jessica Goldthorpe
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 4)

WORK REQUESTED:

Samples of gloves described as 3mil Powder Free Nitrile Examination Glove were received on the 18th March 2019 for testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage. Testing was completed at an external laboratory and reported under their reference 19RA06280.

SAMPLE SUBMITTED

- 3mil Powder Free Nitrile Examination Glove

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail results
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	5.6×10^8 PFU/ml
Post-test bacteriophage titre	5.4×10^8 PFU/ml

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

1. GENERAL

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

2. FEES AND PAYMENT

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

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the 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 – December 2016

Report No : CRSSA/25618/16
 Company : GX Corporation Sdn Bhd (Specialty Plant)
 Plot 6497-A, Lorong Haji Abdul Manan, 5 ¾ Milestone,
 Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
 Size : M
 Quantity Tested : 200 pieces
 Test Conducted : Freedom from holes
 Test Method : EN455 Part 1:2000
 Testing Period : 01 Dec 2016 – 07 Dec 2016

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 2

Result : Within AQL

SGS (MALAYSIA) SDN. BHD.



CHEE TUCK CHOON
 B.Sc. MMIC
 SECTION HEAD

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Report No : CRSSA/25619/16
 Company : GX Corporation Sdn Bhd (Specialty Plant)
 Plot 6497-A, Lorong Haji Abdul Manan, 5 ¾ Milestone,
 Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
 Size : M
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 01 Dec 2016 – 07 Dec 2016

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: $\leq 95 \pm 10$ mm	97	97	98	96	98	98	96	98	97	98	98	96	97	98
Length Median: ≥ 240 mm	245	240	245	243	243	243	242	240	250	245	241	248	240	243

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Report No : CRSSA/25620/16
 Company : GX Corporation Sdn Bhd (Specialty Plant)
 Plot 6497-A, Lorong Haji Abdul Manan, 5 ¾ Milestone,
 Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
 Size : -
 Sample Quantity : 26 pieces
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 7 days
 Testing Period : 01 Dec 2016 – 15 Dec 2016

SIZE	SAMPLE NO.	Force at Break, N	
		<u>DURING SHELF LIFE</u>	<u>AFTER CHALLENGE</u>
M	1	9.2	7.6
	2	8.6	7.3
	3	10.0	7.7
	4	8.0	9.0
	5	9.0	8.5
	6	8.8	8.0
	7	8.8	8.8
	8	9.7	8.0
	9	8.3	8.1
	10	8.4	9.1
	11	8.1	7.8
	12	10.3	8.1
	13	9.8	8.6
Median		8.8	8.1
Requirement		≥ 6.0	≥ 6.0

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Report No : CRSSA/25621/16
Company : GX Corporation Sdn Bhd (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan, 5 ¾ Milestone,
Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
Size :
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2006
Testing Period : 01 Dec 2016 – 07 Dec 2016

On testing the samples, the following results were obtained:-

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
M	0.14mg

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June 19, 2010

• TEST REPORT •

PN 90390

CHEMICAL ANALYTICAL SERVICES

Prepared For:
GX Corporation Sdn. Bhd.
Ms. Cho Sow Fong
Lot 6487 Batu 5 ¾, Sementa
Jalan Kapar, 42100 Klang,
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Prepared By:


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Manager, Chemical & Pharmaceutical Services

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June 19, 2010

Ms. Cho Sow Fong
GX Corporation Sdn. Bhd.

Page 1 of 3 – PN 90390

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: One glove sample identified as Powder Free Nitrile Examination Gloves, Blue (SG), Lot# 38R10D001SG.

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	CHEMICAL SOURCE
Carmustine (BCNU)	Bristol-Myers; Lot# 8B4204A; Expiration 02/2011
Cisplatin	Sigma; Lot# 59H3657; Expiration 09/2010
Cyclophosphamide (Cytoxan)	Sigma; Lot# 079K1569; Expiration 12/2011
Dacarbazine (DTIC)	Hospira; Lot# 31301352B; Expiration 03/2011
Doxorubicin Hydrochloride	Teva; Lot# 31308475B; Expiration 08/2011
Etoposide (Toposar)	Teva; Lot# 31303976B; Expiration 9/2011
Fluorouracil	APP; Lot# 204392; Expiration 09/2010
Ifosfamide	Sicor; Lot# 31307334B; Expiration 11/2010
Methotrexate	Hospira; Lot# W064457AA; Expiration 7/2011
Mitomycin C	Sigma; Lot# 109K1268; Expiration 10/2011
Mitoxantrone	Sigma; Lot# 039K1189; Expiration 2/2011
Paclitaxel (Taxol)	Parenta; Lot# 92148304; Exp. 01/2012
Thiotepa	USP; Lot# I; Catalog# 66400; Expiration 12/2011
Vincristine Sulfate	Hospira; Lot# W027139AA; Expiration 11/2010

COLLECTION MEDIA:

The collection media which were selected are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Carmustine 3.3 mg/ml (3,300 ppm)	10% Ethanol Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm ²
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine	229
Cisplatin	199
Cyclophosphamide (Cytoxan)	200
Dacarbazine (DTIC)	320
Doxorubicin Hydrochloride	232
Etoposide (Toposar)	205
Fluorouracil	269
Ifosfamide	200
Methotrexate	303
Mitomycin C	217
Mitoxantrone	242
Paclitaxel (Taxol)	231
Thiotepa	199
Vincristine Sulfate	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for: Powder Free Nitrile Examination Gloves, Blue (SG), Lot# 38R10D001SG.

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m ²)
	#1	#2	#3		
Carmustine	0.071	0.070	0.072	0.071	65.3
Cisplatin	0.070	0.071	0.071	0.071	65.3
Cyclophosphamide (Cytoxan)	0.075	0.070	0.072	0.072	65.3
Dacarbazine (DTIC)	0.071	0.071	0.073	0.072	65.3
Doxorubicin Hydrochloride	0.070	0.069	0.071	0.070	65.3
Etoposide (Toposar)	0.070	0.075	0.072	0.072	65.3
Fluorouracil	0.070	0.072	0.072	0.071	65.3
Ifosfamide	0.069	0.073	0.066	0.069	65.3
Methotrexate	0.068	0.075	0.069	0.071	65.3
Mitomycin C	0.075	0.073	0.070	0.073	65.3
Mitoxantrone	0.069	0.072	0.071	0.071	65.3
Paclitaxel (Taxol)	0.071	0.071	0.070	0.071	65.3
Thiotepa	0.075	0.075	0.070	0.073	65.3
Vincristine Sulfate	0.072	0.075	0.068	0.072	65.3

RESULTS

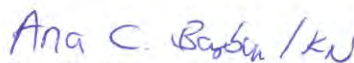
Table 5. Permeation Test Results on: Powder Free Nitrile Examination Gloves, Blue (SG), Lot# 38R10D001SG.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	OTHER OBSERVATIONS
Carmustine	3.48 (2.67,4.67,3.11)	1.71 (1.24,2.36,1.54)	Moderate swelling and no degradation
Cisplatin	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytosan)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa	2.97 (2.42,3.04,3.45)	2.10 (2.09,1.94,2.27)	Slight swelling and no degradation
Vincristine Sulfate	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation



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Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No : GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 1 of 11

TECHNICAL REPORT FOR

**THREE YEAR SHELF LIFE
FOR**

**9" (3 mil) Powder Free Nitrile Gloves
(EN455- 4)**

**[STABILITY STUDY UNDER ACCELERATED AGING
CONDITION]**

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 2 of 11

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Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 3 of 11

1.0 INTRODUCTION

1.1 Purpose

Accelerated aging study was conducted to estimate the product shelf life while pending the completion of the real time aging studies for product expiration dating claim labeling. A maximum shelf life of 3 years shall be assigned based on the accelerated aging studied. The shelf life may be extended as real time aging studies data is generated.

1.2 Scope

This Technical Report covers **9" (3 mil) Powder Free Nitrile Gloves**.

1.3 Summary of work done.

1.3.1 3 lots of sample produced from dipping machine were collected.

1.3.2 Upon completion, the samples were tested in accordance to Shelf Life Study for Accelerated Aging for Medical Gloves – EN 455 Part 4.

1.3.3 Samples of gloves packaged in its consumer packaging were placed in $70\pm 2^{\circ}\text{C}$ air oven for 166 ± 2 hours (7 days) and $50\pm 2^{\circ}\text{C}$ for 90 ± 1 days.

Glove Size	Lot	Lot No	70 \pm 2 $^{\circ}$ C for 166 \pm 2 hours		50 \pm 2 $^{\circ}$ C for 90 \pm 1 days	
			Date Start	Date End	Date Start	Date End
M	Lot 1	20180111-01	1/11/2018	8/11/2018	8/11/2018	6/2/2019
M	Lot 2	20180111-02	1/11/2018	8/11/2018	8/11/2018	6/2/2019
M	Lot 3	20180111-03	1/11/2018	8/11/2018	8/11/2018	6/2/2019

2.0 REFERENCES

- | | | |
|-----|----------------|---|
| 2.1 | EN 455 - 1 | Medical gloves for single use – Part 1: Requirements and testing for freedom from holes |
| 2.2 | EN 455 - 2 | Medical Gloves for single use – Part 2: Requirements and testing for physical properties |
| 2.3 | EN 455 - 4 | Medical Gloves for single use – Part 4: Requirements and testing for shelf life determination |
| 2.4 | ISO : 2859 - 1 | International Standard – Sampling Procedure and Table for Inspection by Attributes B45 |
| 2.5 | PS 037B/16-01 | Product Specification for 9" (3 mil) Gen-X Powder Free Nitrile Gloves (M-3.5g) |

3.0 RESULTS AND DISCUSSION

3.1. Accelerated aging at $70\pm 2^{\circ}\text{C}$ for 166 ± 2 hours and $50\pm 2^{\circ}\text{C}$ for 90 ± 1 days

3.1.1 As shown in Table 1, **all 3 lots** meet the AQL 1.5 requirement for visual test before (control) and after aging (70°C@166 ± 2 hours and 50±2°C (90±1 day) for visual test. This is due to the fact that no blocking, no stickiness issue, no donnability issue and no deterioration on glove were found.

3.1.2 This **Lot 1, Lot 2 and Lot 3** also meet the AQL 1.5 requirement for holes defects before aging (control). After accelerated aging also meet the AQL 1.5 requirement for hole. In addition, accelerated aging at aging does not adversely affect the gloves integrity.

3.1.3 As shown in Table 1, **all lot** meets the EN 455-2 requirement for physical properties (aged). Accelerated aging does enhance the properties of gloves and does not affect the gloves physical properties. From the table it showed that the Force at Break results after aging condition.

3.1.4 Based on Table 1, Physical Dimension before accelerated aging (control) meets the requirement. Accelerated aging condition for **9" (3 mil) Gen-X Powder Free Nitrile Gloves** also would not affect the Physical Dimension test and meets the requirement.

Table 1: Summary of result for visual, water tight test, physical properties and physical dimension

Visual Inspection (G1, AQL 1.5, N=200, Acc-7, Rej-8)									
	Lot 1			Lot 2			Lot 3		
	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days
Blocking	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Stickiness	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Donnability	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Deterioration	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Disposition	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Water Leakage Test (G1, AQL 1.5, N=200, Acc-7, Rej-8)									
	Lot 1			Lot 2			Lot 3		
	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days
Holes/Leak ages	2/200	2/200	2/200	3/200	0/200	4/200	0/200	1/200	3/200
Disposition	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Physical Properties Test (N=13)	
Forced at Break : (Unaged & Aged: Median ≥ 6N)	

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	Control (0 days)			After aging @ 70°C x 166±2 hrs			After aging @ 50°C x 90days		
	Data	Median	Total Reject/ Total Sample	Data	Median	Total Reject/ Total Sample	Data	Median	Total Reject/ Total Sample
Lot 1	6.82 6.82 6.93 6.40 7.54 6.46 6.96 6.80 7.22 7.10 6.48 6.75 6.99	6.82	0/13	7.97 7.50 6.64 7.75 6.15 6.83 7.91 7.69 6.97 8.42 6.47 6.30 6.54	6.97	0/13	7.45 8.07 7.85 6.45 8.46 7.79 6.73 8.25 7.85 8.11 8.21 6.98 8.16	7.85	0/13
Disposition	Pass			Pass			Pass		
Lot 2	6.72 6.70 7.31 6.58 6.58 6.42 6.15 7.10 7.02 7.49 6.58 6.68 6.31	6.68	0/13	6.15 7.69 6.47 7.12 6.29 6.63 7.76 6.60 7.84 7.47 7.65 7.48 7.84	7.47	0/13	7.71 7.33 7.66 7.6 8.11 8.85 8.37 7.89 6.77 8.39 7.32 8.75 8.74	7.89	0/13
Disposition	Pass			Pass			Pass		
Lot 3	6.58 6.60 7.60 7.13 6.62 7.73 6.41 7.89 6.92 7.69 7.43 7.66 7.07	7.13	2/13	6.92 6.32 7.11 6.22 7.12 6.35 7.76 6.57 6.16 6.91 6.93 6.90 6.11	6.90	0/13	9.34 7.00 7.59 8.9 7.84 8.47 8.35 8.47 7.73 8.73 7.37 8.36 6.85	8.35	0/13
Disposition	Pass			Pass			Pass		
Physical Dimension Test Specification (PS 037B/16-01) Cuff Thickness (mm): Min 0.05; Palm Thickness (mm): Min 0.06; Finger Thickness (mm): Min 0.07; Palm width(mm): M: 95±10; Length(mm): Min 240									
	Control (0 days)			After aging @ 70°C x 166±2 hrs			After aging @ 50°C x 90days		
	Data	Median	Total Reject/	Data	Median	Total Reject/	Data	Median	Total Reject/

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			Total Sample			Total Sample			Total Sample
Lot 1									
Cuff Thickness	0.06			0.05			0.05		
	0.06			0.06			0.06		
	0.06			0.06			0.05		
	0.05			0.06			0.06		
	0.05			0.05			0.05		
	0.06			0.06			0.06		
	0.06	0.06	0/13	0.06	0.06	0/13	0.05	0.05	0/13
	0.06			0.06			0.05		
	0.06			0.05			0.05		
	0.06			0.06			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.06			0.05			0.05		
	0.06			0.06			0.05		
Disposition	Pass			Pass			Pass		
Palm Thickness	0.07			0.07			0.07		
	0.07			0.07			0.05		
	0.06			0.06			0.06		
	0.07			0.07			0.05		
	0.07			0.07			0.06		
	0.06			0.06			0.07		
	0.07	0.07	0/13	0.06	0.07	0/13	0.06	0.06	0/13
	0.07			0.07			0.07		
	0.07			0.07			0.06		
	0.07			0.06			0.06		
	0.08			0.07			0.06		
	0.07			0.07			0.07		
	0.07			0.07			0.06		
	0.08			0.07			0.06		
Disposition	Pass			Pass			Pass		
Finger Thickness	0.10			0.12			0.12		
	0.11			0.11			0.12		
	0.12			0.11			0.13		
	0.11			0.12			0.11		
	0.11			0.12			0.13		
	0.12			0.11			0.11		
	0.10	0.11	0/13	0.12	0.11	0/13	0.13	0.12	0/13
	0.10			0.11			0.12		
	0.11			0.10			0.11		
	0.12			0.12			0.13		
	0.12			0.11			0.13		
	0.12			0.12			0.11		
	0.12			0.12			0.12		
	0.11			0.11			0.12		
Disposition	Pass			Pass			Pass		
Palm Width	95			96			96		
	94			95			97		
	95			96			96		
	95			97			97		
	96			95			96		
	95			96			97		
	96	95	0/13	95	96	0/13	95	96	0/13
	96			95			97		
	97			96			96		
	95			97			97		
	95			95			95		
	96			96			96		
	95			97			96		
	95			95			97		
Disposition	Pass			Pass			Pass		

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)							Document Ref. No: GX3-RSL-EN455-4/002-18		
Product Type : 9" (3 mil) Powder Free Nitrile Gloves							Page 7 of 11		

Glove Length	244	245	0/13	245	245	0/13	243	242	0/13
	246			246			241		
	245			242			246		
	245			243			242		
	245			244			241		
	246			244			244		
	245			243			241		
	245			245			242		
	246			246			240		
	245			246			241		
	245			245			244		
	245			246			241		
	245			245			243		
Disposition	Pass			Pass			Pass		
Lot 2									
Cuff Thickness	0.06	0.06	0/13	0.06	0.06	0/13	0.05	0.05	0/13
	0.06			0.06			0.05		
	0.05			0.05			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.07			0.06			0.05		
	0.06			0.07			0.06		
	0.05			0.06			0.05		
	0.06			0.05			0.05		
	0.05			0.06			0.06		
	0.06			0.06			0.05		
	0.05			0.06			0.06		
Disposition	Pass			Pass			Pass		
Palm Thickness	0.07	0.07	0/13	0.07	0.07	0/13	0.07	0.06	0/13
	0.08			0.07			0.06		
	0.08			0.07			0.07		
	0.07			0.06			0.07		
	0.08			0.07			0.06		
	0.07			0.07			0.06		
	0.08			0.07			0.06		
	0.07			0.06			0.06		
	0.07			0.07			0.06		
	0.07			0.06			0.07		
	0.08			0.07			0.05		
	0.08			0.07			0.06		
	0.07			0.06			0.07		
Disposition	Pass			Pass			Pass		
Finger Thickness	0.12	0.11	0/13	0.11	0.11	0/13	0.11	0.12	0/13
	0.10			0.12			0.13		
	0.11			0.12			0.11		
	0.10			0.11			0.12		
	0.12			0.10			0.13		
	0.11			0.11			0.12		
	0.11			0.12			0.11		
	0.12			0.11			0.11		
	0.11			0.11			0.12		
	0.10			0.12			0.13		
	0.13			0.11			0.13		
	0.12			0.12			0.12		
	0.12			0.11			0.11		
Disposition	Pass			Pass			Pass		
Palm Width	96	96	0/13	95	96	0/13	96	96	0/13
	95			96			96		

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)							Document Ref. No: GX3-RSL-EN455-4/002-18		
Product Type : 9" (3 mil) Powder Free Nitrile Gloves							Page 8 of 11		

	95			97			97		
	96			96			95		
	95			96			96		
	96			97			97		
	95			95			96		
	95			96			96		
	96			97			97		
	97			95			97		
	96			96			97		
	95			97			96		
	96			95			97		
Disposition	Pass			Pass			Pass		
Glove Length	245			245			244		
	245			244			241		
	244			245			240		
	245			246			244		
	246			246			243		
	245			243			241		
	246	245	0/13	246	245	0/13	241	241	0/13
	245			245			243		
	245			244			241		
	246			246			241		
	245			245			243		
	246			246			241		
	245			245			243		
Disposition	Pass			Pass			Pass		
Lot 3									
Cuff Thickness	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.07			0.05			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.05		
	0.07			0.06			0.06		
	0.06	0.06	0/13	0.07	0.06	0/13	0.05	0.05	0/13
	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.05			0.07			0.05		
	0.05			0.06			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.06		
Disposition	Pass			Pass			Pass		
Palm Thickness	0.07			0.07			0.07		
	0.07			0.07			0.07		
	0.08			0.06			0.06		
	0.07			0.07			0.07		
	0.07			0.07			0.07		
	0.07			0.07			0.06		
	0.08	0.07	0/13	0.06	0.07	0/13	0.05	0.06	0/13
	0.07			0.07			0.06		
	0.07			0.07			0.07		
	0.07			0.06			0.06		
	0.08			0.07			0.07		
	0.07			0.07			0.06		
	0.07			0.07			0.05		
Disposition	Pass			Pass			Pass		
Finger Thickness	0.12			0.11			0.11		
	0.11	0.11	0/13	0.12	0.11	0/13	0.13	0.12	0/13
	0.12			0.11			0.11		
	0.10			0.12			0.12		

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)							Document Ref. No: GX3-RSL-EN455-4/002-18		
Product Type : 9" (3 mil) Powder Free Nitrile Gloves							Page 9 of 11		

	0.12			0.11			0.13		
	0.10			0.11			0.11		
	0.10			0.12			0.13		
	0.12			0.11			0.12		
	0.12			0.12			0.1		
	0.11			0.12			0.13		
	0.10			0.11			0.12		
	0.12			0.11			0.11		
	0.11			0.11			0.13		
Disposition	Pass			Pass			Pass		
Palm Width	95			95			96		
	96			96			97		
	97			95			95		
	96			96			96		
	96			97			96		
	97			95			97		
	96	96	0/13	96	96	0/13	95	96	0/13
	97			97			97		
	95			95			96		
	96			96			97		
	97			97			97		
	95			95			96		
	96			95			97		
Disposition	Pass			Pass			Pass		
Glove Length	246			246			242		
	241			245			240		
	242			244			243		
	244			246			241		
	246			241			243		
	245			244			241		
	246	246	0/13	240	245	0/13	242	242	0/13
	246			245			244		
	246			245			241		
	244			244			243		
	246			246			242		
	243			245			240		
	246			245			244		
Disposition	Pass			Pass			Pass		

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 10 of 11

4.0 CONCLUSION

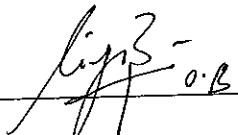
Based on result summary on Table 1, **9" (3 mil) Gen-X Powder Free Nitrile Gloves** meet as per EN 455-4 requirement and shall be labeled with 3 years of expiration date.

- 4.1 No adverse effect on visual defect was found under accelerated aging condition: 70°C@166±2hrs and 50°C@90±1days. The gloves meet the AQL 1.5 requirement for visual inspection.
- 4.2 No blocking, good donnability, no stickiness issue and deterioration on gloves were found under each accelerated aging condition.
- 4.3 No adverse effect on holes defect was found under accelerated aging condition (70°C@166±2hrs and 50°C@90±1days). The gloves meet the AQL 1.5 requirement for hole.
- 4.4 The gloves after each accelerated aging condition meet the EN 455-2 requirements for physical properties after accelerated aging.
- 4.5 This result of this accelerated aging study are applicable for all companies under Smart Glove Corporation Sdn. Bhd.

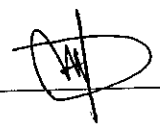
5.0 RECOMMENDATIONS

- 5.1 To conduct real time aging study to confirm the expiration date of 3 years and continue real time study up to 5 years.
- 5.2 Any extension of shelf life beyond 3 years shall be based on real time data

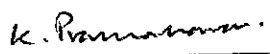
Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 11 of 11

Prepared By : 
Name : Ms. Nur Nabillah
Position : QA Engineer

Date : 12/2/2019

Verified By :  am
Name : Ms. Nurul Ain
Position : QA Manager

Date : 12/02/2019.

Verified By : 
Name : Mr. Prabhakaran
Position : Deputy General Manager
Research & Development

Date : 12/2/2019

DECLARATION OF CONFORMITY

MANUFACTURER

: GX Corporation Sdn Bhd (SpecialtyPlant)
Plot 6497-A, Lorong Haji Abdul Manan,
5 ¾ Milestone, Sementa, Jalan Kapar,
42100 Klang, Selangor Darul Ehsan
Tel: 603-32916100
Fax: 603-32917526

Declares that the Personal Protective Equipment (PPE) described hereafter
3mil Nitrile Examination Gloves
4mil Nitrile Examination Gloves

Is in conformity with the provision of Regulation (EU) 2016/425 and, compliance with the national standard transposing harmonized standard number EN 420, EN 420:2003+A1:2009, EN 16523:2015, EN 374-4:2013, EN ISO 374-1:2016 and EN ISO 374-5:2016 (ISO 16604:2004).

Is identical to the PPE which is the subject of EU Type Examination Certificate issued by:

SATRA Technology Europe Ltd,
Bracetown Business Park, Clonee,
County Meath, D15 YN2P, Ireland.

NB number: 2777

Is subject to the procedure set out in Module C2 Category III of Compliance with Annex II of Regulation (EU) 2016/425

Yours Sincerely,



Name : Poppy Farah Rosa
Position : RA Manager
Date : May 11, 2019

DECLARATION OF CONFORMITY

MANUFACTURER : GX Corporation Sdn Bhd (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul manan,
5 ¾ Milestone, Sementa, Jalan Kapar,
42100 Klang, Selangor Darul Ehsan
Tel: 603-32918668

EUROPEAN REPRESENTATIVE : Mdi Europa GmbH
Langenhanger Str. 71
30855 Langenhagen
Germany.

PRODUCT : Powder Free Nitrile Examination Gloves

CLASSIFICATION : Class I

CONFORMITY ASSESSMENT ROUTE : Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

APPLIED HARMONIZED STANDARD : EN 455-1:2000
EN 455- 2: 2009+A2:2013, EN455- 3:2006
EN 455 -4:2009

PLACE OF ISSUE : GX Corporation Sdn Bhd (Specialty Plant)
Selangor, Malaysia

SIGNATURE :



Name : Poppy Farah Rosa
Position : RA Manager
Date : March 22, 2019

EC DECLARATION OF CONFORMITY

MANUFACTURER : Smart Glove Corporation Sdn. Bhd.
Lot 6487, Batu 5 ¾, Sementa
Jalan Kapar, 42100 Klang
Selangor Darul Ehsan
Tel: 603-32916100
Fax: 603-32917526

EUROPEAN REPRESENTATIVE : mdi Europa GmbH
Langenhanger Str. 71
30855 Langenhagen, Germany.
Tel: +49-511 39 08 95 30
Fax: +49-511 39 08 95 39

PRODUCT : Latex and Nitrile Examination Gloves

CLASSIFICATION : Class I

CONFORMITY ASSESSMENT ROUTE : Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

APPLIED HARMONIZED STANDARD : EN 455-1:2000
EN 455- 2: 2015
EN455- 3:2015
EN 455- 4:2009

PLACE, DATE OF ISSUE : Smart Glove Corporation Sdn. Bhd.
Selangor, Malaysia
January 10, 2013

SIGNATURE :



Name : Poppy Farah Rosa
Position: QA/RA Manager
Date : August, 05 2020



Certificate

No. Q6 066104 0006 Rev. 01

Holder of Certificate: **GX CORPORATION SDN. BHD.**

Lot 6491, Batu 5 3/4, Sementa
Jalan Kapar
42100 Klang, Selangor
MALAYSIA

Facility(ies):

GX CORPORATION SDN. BHD.
Lot 6491, Batu 5 3/4, Sementa, Jalan Kapar, 42100 Klang,
Selangor, MALAYSIA

GX CORPORATION SDN BHD (SPECIALTY PLANT)
Plot 6497-A, Lorong Haji Abdul Manan, 5 3/4 Milestone, Sementa,
Jalan Kapar, 42100 Klang, Selangor, MALAYSIA

Certification Mark:



Scope of Certificate: **MANUFACTURE AND SUPPLY OF NON-STERILE
EXAMINATION GLOVE (NATURAL RUBBER AND
SYNTHETIC LATEX GLOVES)**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: MYQMH0619043-721423014

Valid from: 2019-11-01

Valid until: 2022-10-31

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body



ARTWORK APPROVAL

Client :
Brand : GEN-X
Category : Nitrile Powder-Free
Size : XL
Dimension : 240 (L) x 122 (W) x 60 (H) mm
Window : 115 x 40 mm
Paper Quality : 400gsm Greyback
Surface Finishing : Varnish
Job No. : SGI-033-2020 V3 / **SYE-047-F-R3**
Rev. :
Date : 28/09/2020

Colours :
Process/Pantone
C M Y K

Revision Details:

1. R3/ V3 -
A) Add on en-english, de-german, fr-french, es-spanish, it-italian languages.

B) The DoC can be requested by contacting us via www.smartgloveintl.com

SMART GLOVE™
International

Approved By / Authorised Signature / Date



Code	Aw202006226868	*M307	Revision	5	Date	28 / 09 / 2020
Customer	:	Smart Glove			<div><div></div><div>Cyan</div></div> <div><div></div><div>Magenta</div></div> <div><div></div><div>Yellow</div></div> <div><div></div><div>Black</div></div> <div><div></div><div>Pms 3242 C</div></div>	
Brand	:	Gen X NPF 100				
Category	:	Powder Free				
Size	:	XS				
Dimension	:	230 x 122 x 55 mm				
Window	:	115 x 40 mm				
Paper Quality	:	400gsm Greyback				
Symbology Barcode	:	EAN 13			Font Type : -	
Surface Finishing	:	Varnish			Font Point : -	
Prepared By		Verify By		Approved By		
Tiong Tat Printing		M307				

Customer : Smart Glove
Brand : Gen X NPF 100
Category : Powder Free
Size : L
Dimension : 290(L) x 254(W) x 240(H) mm
Sheet Size : 496(W) x 1118(L) mm

TT Code : TT
Board Quality : TL175 / M150 / 175 BF
Symbology Barcode : -
Colour : Black
Finishing : Glued

Code	Aw202006226869	M307	Revision	5	Date	09 / 09 / 2020
Prepared By Tiong Tat Printing			Verify By M307		Approved By	
Preprint Spec						
Font Type : -			Font Point : -			

