

Technical sheet

Product: Serix Lite 3.0 Blue Nitril Powder-Free Examination Gloves

Manufacturer: Maxter Glove Manufacturing Sdn Bhd

EC-REP: Supermax Healthcare (Europe)



Serix Lite 3.0 Nitrile Powder-Free Examination Gloves

Description

The gloves are intended to be worn on the hands of healthcare personnel during medical examination procedure to protect cross contamination between healthcare personnel and patient.

Characteristics:

- Powder-Free Nitrile Examination Gloves
- This product is not made from natural rubber latex
- Textured finger. Non-sterile
- Design: ambidextrous with elastic cuff
- Protects against bacteria and fungi
- Color: regular blue
- Packing: 100 pcs/box

Tested and certified for use in:

- Hospitals, Laboratories, Health Care Centers
- Dentistry
- Veterinary Clinics
- Food production and processing
- Cosmetics industry
- Hospitality industry: hotels, restaurants, catering

Instructions for use:

Before usage, inspect the gloves for any defect or imperfections
After use, wearers should visually check the gloves and remove any contamination from the outer surface before removing the gloves from the hands. Alternatively, carefully peel the gloves off the hands so that the contaminated outer gloves do not touch your skin.

Storage:

Store in original packaging in a dry and dark area, protected from ozone.

Technical data:

Size	Length (mm)	Width (mm)	Weight (g)	Thickness Cuff	Thickness Palm	Thickness Fingers	Force at break
XS	240	70 - 79	2.8 ± 0.2	0.05 mm	0.05 mm	0.09 mm	6 N (Before Aging) 6 N (After Aging)
S		80 - 89	2.7 ± 0.2				
M		90 - 99	2.9 ± 0.2				
L		100 - 109	3.1 ± 0.2				
XL		110 - 119	3.4 ± 0.2				

Chemical Permeation:

Code letter	Chemical Permeation ISO 374-1:2016)	(EN	Level	Mean Degradation (%) (En 374-4:2013)	
K	40% Sodium Hydroxide		6	-36.1%	Degradation levels indicate the change in Puncture Resistance of the glove after exposure to the tested chemical.
P	30% Hydrogen Peroxide		1	48.7%	
J	n-heptane		2	51.4%	
T	37% Formaldehyde		5	16.7%	

Certifications and standards:

- EN 455-1:2000, EN455-2:2015, EN 455-3:2015, EN455-4:2009
- EN 420:2003 + A1:2009 (Palm Protection)
- EN ISO 374-1:2016/Type B, EN ISO 374-5:2016
- 2777 Comply to PPE Regulation 2016/425 Cat IIII
- CE 0598 Comply to MDR 2017/745 Class I



LOT 6070
Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru
41050 Klang, Selangor, Malaysia
Tel: 603-33929888 (8 lines) Fax: 603-33923328
E-MAIL: info@maxter.com.my

Date: 06th October 2021

To Whom It May Concern

EC DECLARATION OF CONFORMITY

We, **MAXTER GLOVE MANUFACTURING SDN. BHD.** located at Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru, 41050 Klang, Selangor, Malaysia, declares under our sole responsibility that the medical devices described hereafter as :-

- **Non Sterile Latex Examination Gloves**
- **Non Sterile Nitrile Examination Gloves**

- Are in conformity with the general safety and performance requirements of Annex I Medical Device Regulation (EU) 2017/745 for Class I medical devices.
- Classification: Class I based on Rule 5 transient use, Annex VIII of Medical Device Regulation (EU) 2017/745.
- Are in conformity with the national standard transposing harmonized standard EN 455.
- The gloves are manufactured according to ISO 9001:2015 and EN ISO 13485:2016 Quality Management Systems and certified by Notified Body, SGS United Kingdom Ltd Systems & Services Certification.
- Our Authorized Representative is Supermax Healthcare (Europe) Limited, 38 Main Street, Swords Co. Dublin, Ireland K67 E0A2.



Klang, Selangor
Malaysia

Yap Peak Geeh
QA & Regulatory Affairs Manager

SGS

Certificate MY19/1811030073

The management system of

**Maxter Glove Manufacturing
Sdn. Bhd.**

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425
Module D

For the following activities

Natural Latex, Nitrile Rubber Gloves, Chemical Protective Gloves
Note: All products marked CE0598 must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 04 May 2021 until 04 May 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 March 2024
Issue 3. Certified since 01 July 2019

Authorised by

Tom Tom

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Takomitie 8, FI-00380 Helsinki, Finland
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FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)



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Certificate MY00/51618

The management system of

Maxter Glove Manufacturing Sdn. Bhd.

Lot 6070, Jalan Haji Abdul Manan
6th Mile Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

**Manufacture and Distribution of Non Sterile Natural Latex
and Nitrile Rubber Examination Gloves**

This certificate is valid from 10 May 2021 until 04 May 2024 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 04 March 2024
Issue 14. Certified since 04 May 2000

The audit leading to this certificate commenced on 01 March 2021
Previous issue certificate validity date was until 04 May 2021

Authorised by

SGS United Kingdom Ltd
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HC SGS 13485 2016 0118

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Certificate MY00/51619

The management system of

Maxter Glove Manufacturing Sdn. Bhd.

Lot 6070, Jalan Haji Abdul Manan
6th Miles Off Jalan Meru, 41050 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

**Manufacture and Distribution of Non Sterile Natural Latex and Nitrile
Rubber Examination Gloves**

This certificate is valid from 04 May 2021 until 04 May 2024 and
remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 11. Certified since 04 May 2000

Authorised by

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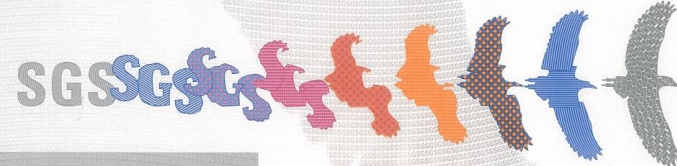
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Shelf Life Determination (Real Time Study) Test Report

1. Purpose:

To determine the shelf life for examination gloves in its final configuration.

2. Scope :

This study covers 2.2 Mil Powder Free Nitrile Examination Gloves produced at Maxter Glove Manufacturing Sdn. Bhd. The study serves to determine the shelf life of gloves based on real time aging study.

The need for an expiration date is primarily based on the potential for a critical aspect of the product to deteriorate, resulting in a patient/user safety risk.

3. Referenced Documents:

EN 455-1: Requirements and testing for freedom from holes.
EN 455-2:2009+A1:2011(E) Requirements and testing for physical properties.
EN 455-4: 2009 Requirements and testing for shelf life determination.
(Annex A method for the determination of shelf life by real time stability studies)

4. Shelf life claims shall not exceed 3 years based on accelerated aging study and not more than 5 years based on real time aging study.

Shelf Life Determination (Real Time Study) Test Report

5. Test Procedure :-

a) Real Time Aging (Stability Test)

(i) Sufficient number of gloves shall be placed in a specified environment and conditioned to assess at intervals of one year or less. Pack 3 lots of gloves in its final packaging configuration.

(ii) Record the manufacturing batch no., date of manufacture (time zero) of these lots of gloves and its packing lot no.

(iii) Store the gloves under actual warehouse conditions (uncontrolled environment). Indicate the location of warehouse, average annual temperature & humidity of warehouse.

(iv) The lots of gloves shall be tested individually and meet requirements of the appropriate EN Standard with respect to freedom from holes, gloves dimension and force at break testing (Refer Table 1).

Table 1 :

No of sample (pcs.)	Freedom from holes		Median of Force at Break (Aged)		Dimensions (width, length, thickness)	
	According to ISO 2859-1 Inspection level G1, AQL 1.5		Min. Req. ≥ 6 N			
	Acc	Rej	Acc	Rej	Acc	Rej
200	7	8	-	-	-	-
13	-	-	Median value ≥ 6 N	Median value < 6 N	Median value meet minimum requirements	Median value does not meet minimum requirements

(v) Testing shall be performed continuously at a minimum yearly interval up to five years for these 3 lots of gloves. Each lot must pass all the requirements of the test as stated in Table 1 to allow a shelf life claim for the stated interval. However, no glove shall be labeled with an expiration date for more than 5 years from its date of manufacture.

(vi) Upon completion of the above procedures, the shelf life claim shall be up to that period, not to exceed five years, for which the gloves have complied with the requirements of the EN455-4 standard.



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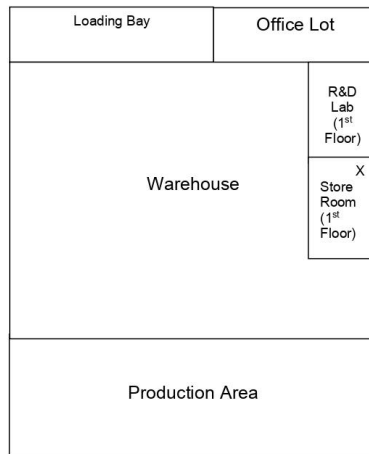
Shelf Life Determination (Real Time Study) Test Report

6 Sample Details :-

Type of glove : **2.2 Mil Powder Free Nitrile Examination Gloves**
Size : **Medium**
Production : **Line 3**

Production batch no.	B12/150/3	A5/59/3	A11/137/3
Packing batch no.	80222 38615	80222 38616	80222 38617
Manufacturing date	15/6/2010	15/6/2010	15/6/2010
Production Time	10am	5pm	11pm
Compounding Batch	120-2010H14-2789	120-2010H14-2790	120-2010H14-2791
TSC %	12.85%	12.77%	12.74%
Compounding Date	14/6/2010	14/6/2010	14/6/2010
Maturation Hours	26 Hours	27 Hours	26 Hours

7. Location of sample :



X - indicates the location of glove sample.



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Shelf Life Determination (Real Time Study) Test Report

8. Test Result

Time Interval	Date of Testing	Temperature	Humidity
Time Zero	16/6/2010	Ambient (29°C)	Ambient (81%)

1. Batch no : 80222 38615

a) Freedom from Holes

Date of Testing:

Gloves	Sample size and specification
80222 38615	Sample size: Inspection Level G-1, but not less than 200 gloves. AQL = 1.5
Conclusion	Watertight test undertaken: 1 defect observed. Pass Inspection criteria : Ac/Re : 7/8

b) Force at Break

Sample no	Force at Break (N)
Sample 1	6.54
Sample 2	6.32
Sample 3	7.17
Sample 4	6.22
Sample 5	6.59
Sample 6	6.77
Sample 7	6.14
Sample 8	6.13
Sample 9	6.87
Sample 10	6.33
Sample 11	6.74
Sample 12	6.55
Sample 13	6.15
EN-455-2	6.0 N
Median	6.54 N
Conclusion : Pass	

c) Dimension (width, length, thickness)

Sample no	Length (mm)	Width (mm)	Thickness (mm)		
			Cuff	Palm	Finger
Sample 1	243	94	0.05	0.06	0.09
Sample 2	240	94	0.05	0.06	0.11
Sample 3	242	94	0.05	0.06	0.10
Sample 4	246	94	0.05	0.05	0.10
Sample 5	243	93	0.05	0.05	0.11
Sample 6	244	94	0.05	0.06	0.10
Sample 7	240	95	0.05	0.06	0.09
Sample 8	243	93	0.05	0.05	0.10
Sample 9	243	94	0.05	0.06	0.10
Sample 10	245	92	0.05	0.06	0.11
Sample 11	241	93	0.05	0.05	0.10
Sample 12	240	94	0.05	0.05	0.09
Sample 13	245	95	0.05	0.05	0.11
EN-455-2	240 min	95±10	-	-	-
Median	243	94	0.05	0.06	0.10
Conclusion	Pass	Pass	Pass	Pass	Pass

Test Report No. : CRSSA/200539200-CA37890
Company : Maxter Glove Manufacturing Sdn Bhd
Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru,
41050 Klang, Selangor Darul Ehsan, Malaysia.

TEST REPORT


Sample Description : Nitrile Powder Free Examination Gloves
 (2.2mil – Cobalt Blue, Purple Blue, Regular Blue, Sky Blue, White, Orange, Clear)
 Lot No. : B0012 14795
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 200 pieces
 Test Conducted : Freedom from holes
 Test Method : EN455 Part 1:2000
 Testing Period : 15 May 2020 – 02 June 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 0

Result : Within AQL

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 SECTION HEAD
 IKM No. M/3983/6401/12/14

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SGS (Malaysia) Sdn Bhd
 (Company No. 10871-1)

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Test Report No. : CRSSA/200539200-CA37890
Company : Maxter Glove Manufacturing Sdn Bhd
Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru,
41050 Klang, Selangor Darul Ehsan, Malaysia.

TEST REPORT

Sample Description : Nitrile Powder Free Examination Gloves
 (2.2mil – Cobalt Blue, Purple Blue, Regular Blue, Sky Blue, White, Orange, Clear)
 Lot No. : B0012 14795
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 15 May 2020 – 02 June 2020

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: 95±10mm	95	95	95	95	95	95	95	95	95	95	95	95	95	95
Length Median: ≥ 240mm	240	250	247	253	248	250	241	243	241	245	247	245	244	245

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 Company : Maxter Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru,
 41050 Klang, Selangor Darul Ehsan, Malaysia.

TEST REPORT

Sample Description : Nitrile Powder Free Examination Gloves
 (2.2mil – Cobalt Blue, Purple Blue, Regular Blue, Sky Blue, White, Orange, Clear)
 Lot No. : B0012 14795
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 13 pieces per each
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 168 hrs
 Testing Period : 15 May 2020 – 02 June 2020

SIZE	SAMPLE NO.	Force at Break, N	
		BEFORE AGING	AFTER AGING
M	1	7.4	7.5
	2	7.2	6.5
	3	8.0	7.4
	4	7.3	7.6
	5	6.8	7.5
	6	7.3	6.8
	7	7.3	7.2
	8	7.2	7.6
	9	7.7	7.8
	10	7.2	7.7
	11	7.6	8.3
	12	7.3	7.8
	13	7.2	8.0
Median		7.3	7.6
Requirement		≥ 6.0	≥ 6.0

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Test Report No. : CRSSA/200539200-CA37890
 Company : Maxter Glove Manufacturing Sdn Bhd
 Lot 6070, Jalan Haji Abdul Manan, 6th Miles Off Jalan Meru,
 41050 Klang, Selangor Darul Ehsan, Malaysia.


TEST REPORT

Sample Description : Nitrile Powder Free Examination Gloves
 (2.2mil – Cobalt Blue, Purple Blue, Regular Blue, Sky Blue, White, Orange, Clear)
 Lot No. : B0012 14795
 Manufacturer : Maxter Glove Manufacturing Sdn Bhd
 Size : Medium
 Quantity Tested : 5 pieces
 Test Conducted : Powder Content
 Test Method : EN455 Part 3:2015
 Testing Period : 15 May 2020 – 02 June 2020

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

SIZE	Average Powder Mass per Glove
M	0.30mg

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Customer details: Maxter Glove Manufacturing Sdn Bhd
Lot 6070
Jalan Haji Abdul Manan
6th Miles off Jalan Meru
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509/1844/JH
/AA/Final

Your reference:

Date of report: 19th December 2018

Samples received: 12th November 2018

Date(s) work carried out: 15th to 20th November 2018

TECHNICAL REPORT

Subject: Chemical innocuousness testing in accordance with EN 420: 2003 + A1: 2009 on gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves, 2.5mil (3.2g-3.6g) Powder Free Nitrile Examination Gloves, 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves and 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Gloves

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: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 7)

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

WORK REQUESTED:

Samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves, 2.5mil (3.2g-3.6g) Powder Free Nitrile Examination Gloves, 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves and 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Gloves were received on the 12th November 2018 for testing in accordance with the innocuousness requirements of EN 420:2003 + A1:2009 Protective Gloves - General Requirements and Test Methods.

SAMPLES SUBMITTED



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Cobalt blue]



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Purple blue]



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Regular blue]



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Sky blue]



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [White]



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Clear]

Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/AA/Final
Date: 19th December 2018

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Signed:



Samples described as 2.5mil (3.2g-3.6g) Powder Free Nitrile Examination Gloves [Pink]

Samples described as 2.5mil (3.2g-3.6g) Powder Free Nitrile Examination Gloves [Teal]

Samples described as 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves [Blue]



Samples described as 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves [Black]

Samples described as 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves [Ice blue]

Samples described as 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Gloves [Orange]

CONCLUSIONS:

As required under clause 4.3.1 General innocuousness of protective gloves, the samples of gloves described as 2.2mil (2.7g-3.1g), 2.5mil (3.2g-3.6g) Powder Free Nitrile Examination Gloves, 3.2mil (3.3g-3.7g) Powder Free Nitrile Examination Gloves and 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Glove Powder Free Nitrile Examination Gloves were found to meet the REACH annex XVII requirement for PAHs.

Full results are reported in the following tables.

TESTS REQUIRED:

- #SATRA SOP CAT-018 – Determination of PAHs (based on ZEK 01.4-08)

RESULTS AND REQUIREMENTS:

SATRA SOP CAT-018 – Determination of PAHs

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

Sample	PAHs detected (mg/kg)	Pass/Fail
Cobalt blue, Purple blue and Regular blue combined	<0.2 (of each PAH listed in the appendices)	Pass
Sky blue, White and Clear combined	<0.2 (of each PAH listed in the appendices)	Pass
Bluple, black and ice blue combined	<0.2 (of each PAH listed in the appendices)	Pass
Pink, Teal and Orange combined	<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	-

Results for 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Gloves [Orange] are applicable to 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Orange] as confirmed by Maxter Glove Manufacturing Sdn Bhd.

Results for 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves [Regular blue] are applicable to 3.2mil (3.3g-3.6g) Powder Free Nitrile Examination Gloves [Regular Blue] as confirmed by Maxter Glove Manufacturing Sdn Bhd.

Results for 3.2mil (3.3g-3.6g) Powder Free Nitrile Examination Gloves [Black] are applicable to 7.0mil (8.2g-8.6g) Powder Free Nitrile Examination Gloves [Black] as confirmed by Maxter Glove Manufacturing Sdn Bhd.

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	

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Date: 19th December 2018 (Page 3 of 7)

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Date: 19th December 2018 (Page 4 of 7)

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Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/AA/Final
Date: 19th December 2018 (Page 5 of 7)

Signed:

Customer details: Maxter Glove Manufacturing Sdn Bhd
Lot 6070
Jalan Haji Abdul Manan
6th Miles off Jalan Meru
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509/1844/JH
/H

Your reference:

Date of report: 19th December 2018

Samples received: 12th November 2018

Date(s) work carried out: 27th November to 7th December 2018

TECHNICAL REPORT

Subject: EN 16523-1: 2015 resistance to permeation by chemicals on gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves

WORK REQUESTED:

Samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves were received by SATRA on the 12th November 2018 for testing in accordance with EN 16523-1:2015 and assessment in accordance with the requirements of EN ISO 374-1: 2016.

SAMPLES SUBMITTED:



Samples described as 2.2mil (2.7g-3.1g)
Powder Free Nitrile Examination Gloves

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016 the samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves achieved the following performance levels:

Chemical	Performance level
25% Ammonium hydroxide (CAS: 1336-21-6)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
65% Nitric acid (CAS: 7697-37-2)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved*
30% Hydrogen peroxide (CAS: 7722-84-1)	1
37% Formaldehyde (CAS: 50-00-0)	5

* The conductivity of the collection medium rose above the working range of the detection system. However before this point a breakthrough had not occurred.

Full results are reported in the following tables.

Conditions of Issue:

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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 a coverage probability of approximately 95%.

Report signed by: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 10)

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Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018

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(Page 2 of 10)

TESTING REQUIRED:

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

RESULTS AND REQUIREMENTS:

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

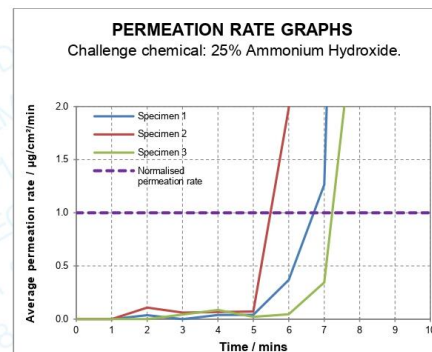
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

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SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018 (Page 3 of 10)

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Test/Property	Sample reference:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves	Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 25% Ammonium hydroxide	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)	
Using PTFE permeation cells with standardised dimensions	Specimen	Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)	
		Test temperature: (23 ± 1) °C	
		Thickness (mm)Δ	
		Breakthrough time (mins)	
	1	0.05	7
	2	0.04	6
	3	0.04	8
		Test result:	6
		UoM:	<1
Visual appearance of specimens after testing:		Swollen and discoloured	

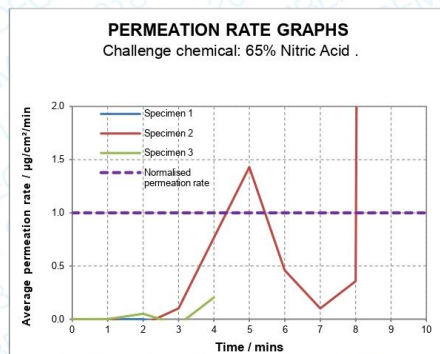


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Date: 19th December 2018 (Page 4 of 10)

Signed:

Test/Property	Sample reference:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	65% Nitric acid	
		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%)	
Using PTFE permeation cells with standardised dimensions	Specimen	Test temperature:	(23 ± 1) °C	
		Thickness (mm)Δ	Breakthrough time (mins)	
		1	0.05	
		2	0.05	
		3	0.04	
Visual appearance of specimens after testing:		Test result:	4*	
		UoM:	<1	
		Swollen, disintegrated, discoloured and hardened		

* The conductivity of the collection medium rose above the working range of the detection system. However before this point a breakthrough had not occurred.



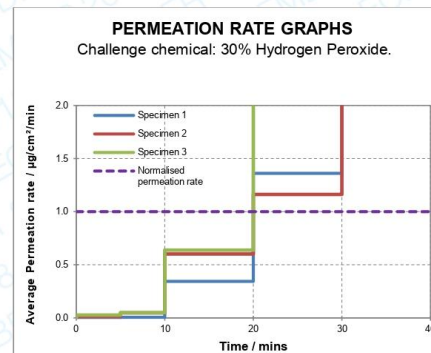
The reading from specimen 2 after 5 minutes was considered to be an outlier and not a breakthrough.

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SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018 (Page 5 of 10)

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Test/Property	Sample reference:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves		Performance
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		Level 1
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
Using PTFE permeation cells with standardised dimensions	Specimen	Test temperature: (23 ± 1) °C		
		Thickness (mm)△	Breakthrough time (mins)▼	
		1 0.04	Between 21 to 30	
		2 0.05	Between 21 to 30	
	3 0.04	Between 21 to 30		
		Test result:	Between 21 to 30	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and discoloured		

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



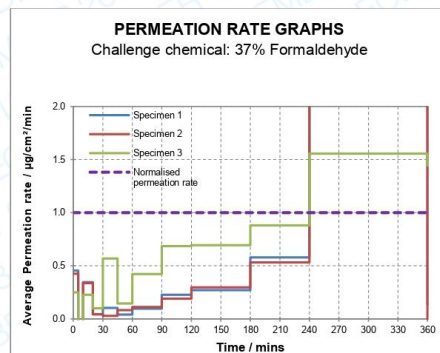
Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

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SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018 (Page 6 of 10)

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Test/Property	Sample reference:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves		Performance	
EN 16523-1:2015 in accordance with SATRA SOP CAT-025	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			
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)△	Breakthrough time (mins)▼		
		1	0.04		Between 241 to 360
		2	0.04		Between 241 to 360
		3	0.04		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.

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SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018

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

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

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SATRA Reference: CHM0277509/1844/JH/G
Date: 19th December 2018

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6th Miles off Jalan Meru
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509/1844/JH
/J

Your reference:

Date of report: 19th December 2018

Samples received: 12th November 2018

Date(s) work
carried out: 3rd to 6th December
2018

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 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves

Conditions of Issue:

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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: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 5)

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TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves were received on the 12th November 2018 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 18RA15944.

Test specimens were selected from the white, regular blue and purple blue colour variants.

SAMPLE SUBMITTED



Samples described as 2.2mil (2.7g-3.1g)
Powder Free Nitrile Examination [White]



Samples described as 2.2mil (2.7g-3.1g)
Powder Free Nitrile Examination [Regular
blue]



Samples described as 2.2mil (2.7g-3.1g)
Powder Free Nitrile Examination [Purple
blue]

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SATRA Reference: CHM0277509/1844/JH/J
Date: 19th December 2018

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Signed:

TECHNICAL REPORT

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	Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	6.3x10 ⁸ PFU/ml
Post-test bacteriophage titre	6.2x10 ⁸ PFU/ml

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Date: 19th December 2018

(Page 3 of 5)

Signed:

Customer details: Maxter Glove Manufacturing Sdn Bhd
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6th Miles off Jalan Meru
41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509/1844/JH
/I

Your reference:

Date of report: 19th December 2018

Samples received: 12th November 2018

Date(s) work carried out: 27th to 29th November 2018

TECHNICAL REPORT

Subject: EN 374-4:2013 determination of resistance to degradation by chemicals on gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.

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 a coverage probability of approximately 95%.

Report signed by: Jade Hurley
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 6)

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WORK REQUESTED:

Samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves were received on the 12th November 2018 for testing in accordance with EN 374-4:2013.

SAMPLES SUBMITTED:



Samples described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.

CONCLUSION:

When assessed in accordance with EN 374-4:2013 the samples of gloves described as 2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves achieved the following degradation results:

Chemical	Mean degradation / %
25% Ammonium hydroxide (CAS: 1336-21-6)	86.3
65% Nitric acid (CAS: 7697-37-2)	100.0
30% Hydrogen peroxide (CAS: 7722-84-1)	48.7
37% Formaldehyde (CAS: 50-00-0)	16.7

TESTING REQUIRED:

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

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SATRA Reference: CHM0277509/1844/JH/I
Date: 19th December 2018

(Page 2 of 6)

Signed:

RESULTS:

Sample description:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.		
Challenge chemical:	25% Ammonium hydroxide (CAS: 1336-21-6)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	88.1	81.4	89.3
Mean degradation (DR) / %:	86.3		
Standard deviation (σ_{DR}) / %:	4.3		
UoM / ± %:	66.6		
Appearance of samples after testing:	Swollen and discoloured		

Sample description:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.		
Challenge chemical:	65% Nitric acid (CAS: 7697-37-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	100.0	100.0	100.0
Mean degradation (DR) / %:	100.0		
Standard deviation (σ_{DR}) / %:	0.0		
UoM / ± %:	N/A		
Appearance of samples after testing:	Swollen, disintegrated, discoloured and softened		

Sample description:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	45.7	48.6	51.8
Mean degradation (DR) / %:	48.7		
Standard deviation (σ_{DR}) / %:	3.1		
UoM / ± %:	21.3		
Appearance of samples after testing:	Swollen		

Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/I
Date: 19th December 2018

(Page 3 of 6)

Signed:



Sample description:	2.2mil (2.7g-3.1g) Powder Free Nitrile Examination Gloves.		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
	39.1	16.0	-5.0
Mean degradation (DR) / %:	16.7		
Standard deviation (σ_{DR}) / %:	22.1		
UoM / ± %:	16.5		
Appearance of samples after testing:	Swollen		

Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509/1844/JH/I
Date: 19th December 2018

(Page 4 of 6)

Signed:



Customer details: Maxter Glove Manufacturing Sdn Bhd
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Jalan Haji Abdul Manan
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41050 Klang
Selangor
Malaysia

SATRA reference: CHM0277509 /1844
/SPT /2

Your reference:

Date of report: 22 November 2018

Samples received: 12 November 2018

For the attention of: Yap Peak Geeh

Date(s) work carried out: 21 November 2018

TECHNICAL REPORT

Subject: Testing of gloves identified as 2.2 mil (2.7g-3.1g) powder free nitrile examination gloves in accordance with EN 420:2003+A1:2009 clause 5 Sizing and Dexterity and EN 374-2:2014

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: Sue Clayton
Position: Technologist
Department: Safety Product Testing

(Page 1 of 6)

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Work Requested

Samples of gloves, see Table 1, were received by SATRA for testing in accordance with EN 420:2003+A1:2009 Protective gloves - General requirements and test methods, clauses 5.1 Sizing and 5.2 Dexterity only, and EN 374-2:2014 Protective gloves against dangerous chemicals and microorganisms - Determination of resistance to penetration.

Table 1 – Samples received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
2.2 mil (2.7g-3.1g) powder free nitrile examination gloves	S – XL XS – XL	Purple blue Cobalt blue	Size: XS Weight: 2.7 g



2.2 mil (2.7g-3.1g) powder free nitrile examination gloves

Conclusion

Standard	Clause / Property	Result
EN 420:2003+A1:2009	5.1 Sizing	See Note ■
	5.2 Dexterity	Level 5
EN 374-2:2014	7.2 Air leak test	See Note ●
	7.3 Water leak test	PASS

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

Note ● – As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the Air leak test. Therefore, as per EN 374-2, only the Water leak test has been performed.

Maxter Glove Manufacturing Sdn Bhd
SATRA Reference: CHM0277509 /1844 /SPT /2
Date: 22 November 2018 (Page 2 of 6)

Signed:

Sue Clayton

Testing

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

Requirements

Table 2 – Requirements for EN 420:2003 + A1:2009 Clause 5 Sizing and Dexterity

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

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

Table 3 - Requirements for EN 374-2: 2014

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

Test Results

Table 4 - EN 420:2003 + A1:2009 Test results for gloves identified as 2.2 mil (2.7g-3.1g) powder free nitrile examination gloves

Clause / Test	Test Results		UoM	Result
5.1 Sizing	Size	Length /mm		
		Left	Right	
	XS / 6	245	250	
	Comments on fit: Satisfactory			
	S / 7	250	250	
	Comments on fit: Satisfactory			
	M / 8	245	251	
	Comments on fit: Satisfactory			
	L / 9	259	256	
	Comments on fit: Satisfactory			
	XL / 10	260	255	
	Comments on fit: Satisfactory			
5.2 Dexterity	Size	Minimum pin diameter / mm		
	XS / 6	5.0		
	S / 7	5.0		
	M / 8	5.0		
	L / 9	5.0		
	XL / 10	5.0		

Table 5 - EN 374-2:2014 Test results for gloves identified as 2.2 mil (2.7g-3.1g) powder free nitrile examination gloves

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used:	2.47 kPa		
	Sample size	Leaks		
	XS / 6			
	S / 7			
	M / 8			
	L / 9			
7.3 Water leak test	Sample size	Leaks		
	XS / 6	No leaks detected		
	S / 7	No leaks detected		
	M / 8	No leaks detected		
	L / 9	No leaks detected		
	XL / 10	No leaks detected		

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Signed: 

EU Type-Examination Certificate

Certificate number: 2777/12706-01/E00-00

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

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

Product reference:

PFSN-FTCB
PFSN-FTP
PFSN-FTRB
PFSN-FTSB
PFSN-FTW
PFSN-FTO
PFSN-FTCR

Description:

Non sterile powder free nitrile examination glove, 2.2 mil
Available in colours: Cobalt Blue, Purple Blue, Regular Blue, Sky Blue, White, Orange and Clear

Classification:

EN ISO 374-1:2016 Type B

n-Heptane (J)
Sodium hydroxide 40% (K)
Formaldehyde 37% (T)
Hydrogen peroxide 30% (P)

Level	EN 374-4: 2013
2	51.4%
6	-36.1%
5	16.7%
1	48.7%

Sizes:

Extra Small – 6
Small – 7
Medium – 8
Large – 9
Extra Large – 10

EN ISO 374-5: 2016

Protection against bacteria & fungi
Protection against viruses

Level
Pass
Pass

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

Technical reports/Approval documents:

SATRA: CHM0277509/1844/JH/I, CHM0277509/1844/JH/H, CHM0277509/1844/JH/J, CHM0277509/1844/JH/AA/Final,
CHM0277509/1844/SPT/2
CENTEXBEL: 17.00808.02

Signed on behalf of SATRA:



Tara Holly



Quincey Brown

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Thank you!



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