




EU standard Disposable Powder Free Nitrile Gloves

Executive standard: EN374-1/2/3/4/5



SATRA Technology Services (Singapore) Ltd
Unit 10, Eurologistics Centre, Xing
Road, Singapore Free Zone,
Singapore Province, China
Tel: +65 6349 8888
Email: satrat@satra.com.sg

Customer details:

Changzhou Universal Medical Equipment

Co., Ltd.
No. 1001 Road,
Kincell District,
Changzhou City,
Jiangsu Province,
China

SATRA reference: CHT0358510 / 2049

Your reference: VN-N001

Date of report:	21 December 2020
Samples received:	4 December 2020
Dates of work carried out:	11 December 2020

TECHNICAL REPORT

Subject:

EN ISO 21400: 2020 size & density & microanalysis test, EN ISO 374-2: 2019 gel leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: Blue size: XS, SE, M, L, XL, LXX

Certificate 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 It must not be published, for example by including it in advertisements, without the prior written permission of SATRA.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 made by SATRA or its staff as to the fitness for purpose or suitability for any subsequent tests or change incurred by the client as a result of information supplied in the report.

The uncertainty of the results (U₉₅) 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:
Position: Technologist
Department: Client Testing

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TECHNICAL REPORT

WORK REQUESTED

Supplier: described as Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: blue, size: XS5.
 Supplier: described as Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: blue, size: XS5.
 Supplier: described as Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: blue, size: XS5.
 Supplier: described as Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: blue, size: XS5.

SAMPLE SUBMITTED



<p>Sample described as Disposable Powder free Nitrile gloves referenced as VN-N001, Colour: blue, size: XS5, 56, MT, LB, XL3</p>
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TESTING REQUESTED

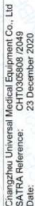
- EN ISO 21420: 2020 Clause 5.1 – String and measurement of gloves
- EN ISO 21420: 2020 Clause 5.2 – Density
- EN ISO 21420: 2020 Clause 5.3 – Thickness
- EN ISO 374-5: 2018 Clause 6.3 – Protection against viruses (ISO 19064: 2004 Procedure B)
- EN 374-2: 2019 Clause 7.2 – A1 leak
- EN 374-2: 2019 Clause 7.3 – Water leak

CONCLUSION


The samples described Disposable Powder free Nitrile gloves referenced as VN-N001, colour: blue, size: XS5.
 Co, MT, LB, XL3 were found to achieve the following results:

- EN ISO 21420: 2020 Clause 5.1 – Size below table
- EN ISO 21420: 2020 Clause 5.2 – Level 5
- EN ISO 21420: 2020 Clause 5.3 – Pass
- EN 374-2: 2019 Clause 7.2 – Pass
- EN ISO 374-5: 2018 Clause 6.3 – Pass
- EN ISO 21420: 2020 Clause 4.2 – Pass PAMs, pH value and DMFA

Detailed results are included on the following page(s)


 Gingstaph Universal Medical Equipment Co., Ltd.
 Address: Reference:
 Date: 23 December 2020

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 He Chao
 2020.12.23



产品简介/Product introduction

欧标民用丁腈手套

EU standard Disposable Powder Free Nitrile Gloves

Executive standard:EN374-1/2/3/4/5

TECHNICAL REPORT

Testing

Testing was carried out in accordance with EN ISO 21420: 2020 and EN 374-2: 2019.

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 - Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

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

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

Clause	7.2 Air leak	7.3 Water leak
Requirement	No leak to be detected	No leak to be detected

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CHT1030508 2249
SATRA Reference: 23 December 2020
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TECHNICAL REPORT

Test Results

Table 3 - EN ISO 21420:2020 Test Results.

Clause / Test	Requirement	Test Results	UoM (See note 4)	Result	
		Size	Length /mm		
5.1 Glove length, comfort and fit	N/A	1	233	234	235
		2	240	240	239
		3	241	241	240
		4	239	239	238
5.2 Dexterity	See table 1	Size	Minimum pin diameter /mm	Level 5	
		5	5.0		
		6	5.0		
		7	5.0		
		8	5.0		

Additional Information / Notes

Note 4 - Estimated accuracy of measurement applied at point of test (e.g. to applied force or to tolerance limit) to ensure product meets requirements of the standard.

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TECHNICAL REPORT

Test Results

Table 4 - EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results	UoM	Result
	Total air pressure used		
7.2 Air leak test	Sample size		
	5	No leaks detected	
	6	No leaks detected	
	7	No leaks detected	NA
7.3 Water leak test	Sample size		
	5	No leaks detected	
	6	No leaks detected	
	7	No leaks detected	NA

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产品介绍/Product introduction

欧标民用丁腈手套

EU standard Disposable Powder Free Nitrile Gloves

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TECHNICAL REPORT

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 209007214. The laboratory is CNAS accredited to ISO 17025:2017 with ISO 15604:2004 included in their accreditation schedule.


Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description:		Disposable Powder free Nitrile gloves reference to VN-K01, colour blue, size: XS, S, M, L, XL					Comment	
Test method	Specimen	Step 1 (0.1 MPa, 5 min)		Step 2 (14 kPa, 1 min)		Step 3 (10kPa, 1 min)	Acceptance (PTU/mL seen)	Comment
		+ control	seen	seen	seen			
ISO 15604:	- control	None seen	None seen	None seen	None seen	None seen	< 1	Acceptable
Procedure B	1	None seen	None seen	None seen	None seen	None seen	< 1	Pass
Using	2	None seen	None seen	None seen	None seen	None seen	< 1	Pass
Screen	3	None seen	None seen	None seen	None seen	None seen	< 1	Pass

Changzhou Universal Medical Equipment Co., Ltd
 CNY1008687 2009
 SATRA Reference:
 02 September 2020
 Date:

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Signed: *Glady's He*
 China SATRA



TECHNICAL REPORT

Innocuousness Testing

Testing was conducted at a third-party laboratory and reported under their reference A201209024091. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
BD1	Disposable Powder-free Nitrile gloves referenced as VM-M001, color: Rte	Gloves	-

pH Value: EN ISO 21488:2018

Test Method 1: WB reference is EN ISO 4045:2018, analyzed by pH meter.

Test Method II: WB reference is ISO 2071:2007, analyzed by pH meter.


Requirement:	3.1.2.5	
Test Items	-	Unit
Test Method	-	BD1
Test Result	-	II
pH Value of Extracting Solution	-	1.48
Temp. of Extracts Extract	deg. C	25.2
Extraction Time	min	2
Difference Liquid	-	2
Conclusion	-	PASS


Note: Key: deg. C = degree Celsius (°C), Temp. = Temperature

Remark: Result(s) was (were) reported the average value from two trials.

Changzhou Universal Medical Equipment Co., Ltd
SATRA Reference: 23040000000000
Date: 23 September 2023

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Signed: 
Gao Jingshi
Company Director



TECHNICAL REPORT

Polyoxalic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21439:2002

Test Method : With reference to test method PQ-CEN ISO/TS 16190:2013

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg			
	Tested Item(s)	Detectable Analyte(s)	Result	Unit
	(ppm)	ND	ND	mg/kg

Note / Key : ND = Not detected (Detection Limit) Detection Limit (mg/kg): Each 1.0; 1.2;

mg/kg = milligram per kilogram ; ppm = part per million

Remark: The total poly-oxalic aromatic hydrocarbons is summarized in table of Appendix

APPENDIX			
List of Poly-oxalic Aromatic Hydrocarbons:		CAHs-No.	C5-6-No.
1	Chrysene	218-61-9	5
2	Benzo (a) pyrene	50-32-6	6
3	Benzo (b) pyrene	115-97-2	7
4	Benzo (k) fluoranthene	156-55-3	8
			205-49-2
			205-45-3
			227-169-9

Dimethylformamide (DMFA) Content - EN ISO 11459:2008

Test Method : With reference to EN 14779:2016, and then analyzed by Gas Chromatography Mass Spectrometry

Analyte	Unit	Result	Client's Requirement
Dimethylformamide (DMFA)	mg/kg	ND	1000
Conclusion		PASS	


Note / Key : ND = Not detected (Detection Limit) Detection Limit (mg/kg) : 5

mg/kg = milligram per kilogram ; ppm = part per million

*** End of Report ***

Changzhou Universal Medical Equipment Co., Ltd
 SATRA Reference: ZT170305089
 Date: 21 October 2020

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Signed  He
 Chen Jiahe





产品简介/Product introduction

欧标民用丁腈手套

EU standard Disposable Powder Free Nitrile Gloves



Executive standard: EN374-1/2/3/4/5



Customer details:

SATRA Technology Services (Dongguan) Ltd
Unit 10, Xingcheng Garden
Hongqiao Road
Nangang District
Guangdong Province
523079

Your reference: CHT035808
Date of report: 25th January 2021
Samples received: 8th December 2020
Date(s) work carried out: 11th to 20th January 2021



Customer: Changzhou Universal Medical Equipment
No. 1, Xing Road,
Xixie District,
Jiangsu Province
China

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd
Customer: Changzhou Universal Medical Equipment

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way & used not be published, for example by including it in a presentation, 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 the client's information only and do not constitute a guarantee of performance.

Tests were performed in accordance with the UKAS Accreditation Scheme for SATRA. All interpretations of results of such tests and the comments based upon them are the sole responsibility of SATRA 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 by SATRA for the use of the product for any purpose other than that for which it was intended.

The uncertainty of the results (k=2) in the 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: Lucy Cove
Position: Technology
Department: Chemical & Analytical Technology

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WORK REQUESTED:

Samples of gloves described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue were received on the 8th December 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:

Samples described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue



CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powder free Nitrile gloves referenced as WN-N001, colour: blue achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	2
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.



TESTING REQUIRED

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

Report signed by: Lucy Cove
Position: Technology
Department: Chemical & Analytical Technology

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SATRA Technology Services (Dongguan) Ltd
Customer: Changzhou Universal Medical Equipment
Date: 25th January 2021



RESULTS AND REQUIREMENTS:

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

Permeation performance level	Measured breakthrough time (minutes)
1	>30
2	>60
3	>120
4	>240
5	>480
6	>960

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

SATRA Technology Services (Dongguan) Ltd
Customer: Changzhou Universal Medical Equipment
Date: 25th January 2021

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Report signed by: Lucy Cove






产品简介/Product introduction


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EU standard Disposable Powder Free Nitrile Gloves

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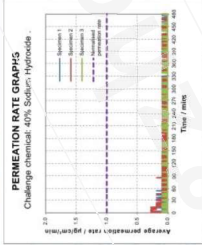
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Test/Property	Sample reference:	Performance
EN 16523-1:2015 +A1:2018 in with SATRA SOP CAT 009	Disposable Powder free Nitrile gloves referenced as EN 374-1:2016 Chemical: as WVA 40% Sodium Hydroxide Normalised permeation rate (NPR): 1 µg/cm ² /min Detection technique: Conductimetry Collection medium: Distilled water (periodic measurement) Collection medium stirring rate: 45 - 65 min/min Test time constant to within ± 10% Test result: Between 10 to 15 min	Level 6
Specimen	Using PTFE with standardised dimensions	Thickness (mm): 1 0.39 3 0.39 Test result: >480
Visual appearance of specimens after testing:	UCL: No change	

PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide




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SATRA Reference: 257 January 2021
Date: (Page 4 of 9)

Signed: *l.me*

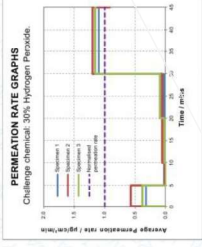
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TECHNICAL REPORT




Test/Property	Sample reference:	Performance
EN 16523-1:2015 +A1:2018 in with SATRA SOP CAT 025	Disposable Powder free Nitrile gloves referenced as EN 374-1:2016 Chemical: as WVA 30% Hydrogen Peroxide Normalised permeation rate (NPR): 1 µg/cm ² /min Detection technique: Electrochemical detection (periodic measurement) Collection medium: Distilled water (periodic measurement) Collection medium stirring rate: 45 - 65 min/min Test time constant to within ± 10% Test result: Between 31 to 45 min	Level 2
Specimen	Using PTFE with standardised dimensions	Thickness (mm): 1 0.39 3 0.10 Test result: Between 31 to 45
Visual appearance of specimens after testing:	UCL: See below	

PERMEATION RATE GRAPHS
Challenge chemical: 30% Hydrogen Peroxide




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Date: (Page 5 of 9)

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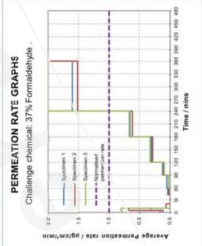
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TECHNICAL REPORT



Test/Property	Sample reference:	Performance
EN 16523-1:2015 +A1:2018 in with SATRA SOP CAT 025	Disposable Powder free Nitrile gloves referenced as EN 374-1:2016 Chemical: as WVA 30% Hydrogen Peroxide Normalised permeation rate (NPR): 1 µg/cm ² /min Detection technique: HPLC-DAD (periodic measurement) Collection medium: Distilled water (periodic measurement) Collection medium stirring rate: 45 - 65 min/min Test time constant to within ± 10% Test result: Between 241 to 360 min	Level 5
Specimen	Using PTFE with standardised dimensions	Thickness (mm): 1 0.39 3 0.39 Test result: Between 241 to 360
Visual appearance of specimens after testing:	UCL: Section and discoloring	

PERMEATION RATE GRAPHS
Challenge chemical: 30% Hydrogen Peroxide



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SATRA Reference: 257 January 2021
Date: (Page 6 of 9)

Signed: *l.me*



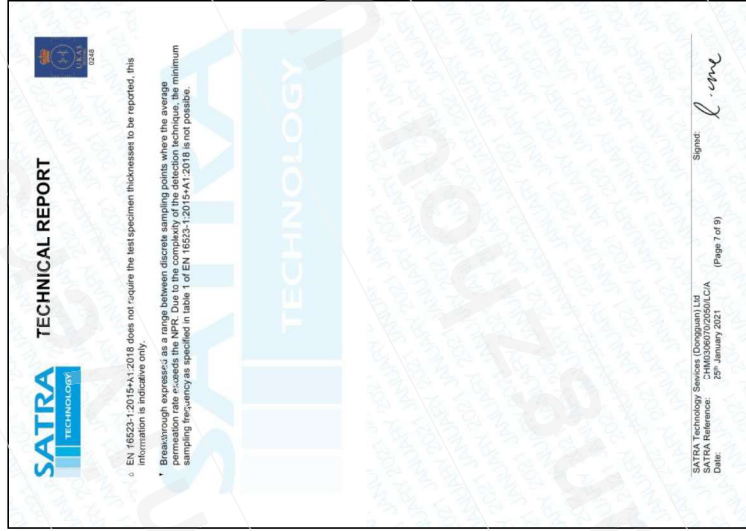


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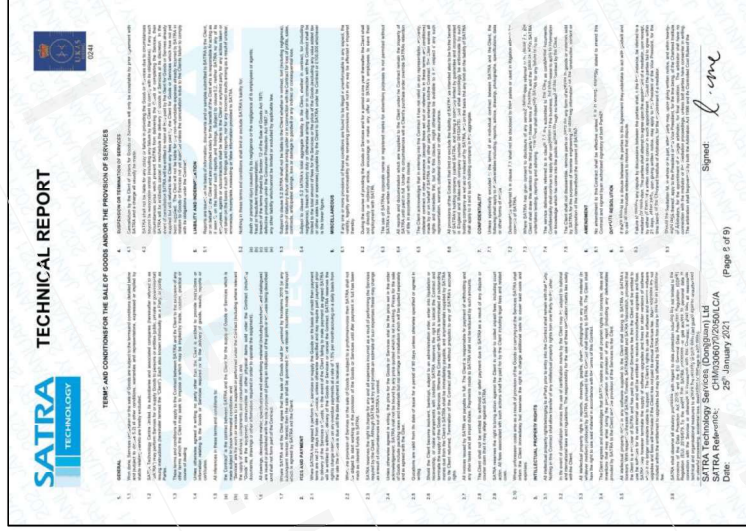
欧标民用丁腈手套

EU standard Disposable Powder Free Nitrile Gloves

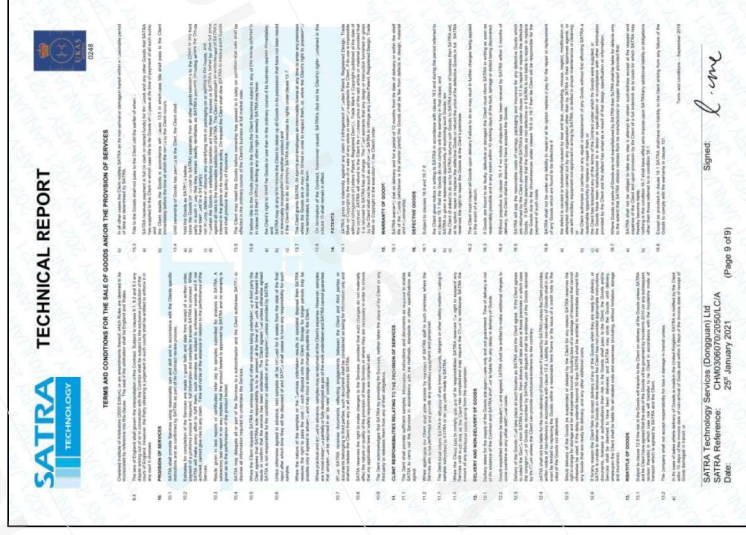
Executive standard: EN374-1/2/3/4/5



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产品介绍/Product introduction

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EU standard Disposable Powder Free Nitrile Gloves

Executive standard: EN374-1/2/3/4/5

SATRA Technology Centre Ltd
Anytown Road
Huntingdon, Cambs PE28 7JL, United Kingdom
Tel: +44 (0) 1354 10000
Fax: +44 (0) 1354 10001
e-mail: info@satra.com
www.satratrading.com

0208

Customer details:

SATRA Technology Services (Dongguan) Ltd
Unit 110,
Hongyue Road
Dongguan City, Guangdong
DONGGUAN CITY
Guangdong Province
523878

SATRA reference: CHM030607020504LC
Your reference: CHT030508

Date of report: 25th January 2021
Samples received: 09th December 2020
Date(s) work: 15th to 21st January 2021
Carried out: 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Chengzhou, Universal Medical Equipment

No. 6, Xian Road,
Xinbei District,
Jiangbei County,
Jiangxi Province
China

Subject:

EN ISO 374-4:2018 determination of resistance to degradation by dangerous chemicals on a pair of gloves. The product is Disposable Free Nitrile gloves identified as TYN-0001, 250071496.

Conditions of test:

These tests may be requested to other countries and therefore it is not changed in the report. It is not published, for reasons of confidentiality and to protect the intellectual property of SATRA.

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

Tests marked 1 fail outside the UKAS Accredited Scope, or SATRA. All interpretations of results of such tests and the comments based on them are outside the scope of UKAS accreditation and are based on current SATRA.

Accreditation

This report is for your information only. The product tested is not accepted by SATRA, and the results of the tests are not a warranty of any product tested. SATRA will 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 (U₉₅) 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:
Name:
Department:

Lucy Cove
Senior Analyst
Chemical & Analytical Technology


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TECHNICAL REPORT



WORK REQUESTED:

Samples of gloves described as Disposable Powder-free Nitrile gloves referenced as VN-N001, colour: blue were received on the 31st December 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Sample described as Disposable Powder free Nitrile gloves referenced as VN-N001, colour: blue.

CONCLUSION:

When increased in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder free Nitrile gloves referenced as VN-N001, colour: blue achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-47.7
30% Hydrogen peroxide (CAS: 7722-84-1)	18.6
37% Formaldehyde (CAS: 50-00-0)	-22.0


TESTING REQUESTED:

- EN ISO 374-4:2019 Protective gloves against dangerous chemicals and micro-organisms.
- Part 4: Determination of resistance to degradation by chemicals.


Date: _____
SATRA Technology Services (Uppington) Ltd
SATRA Reference: CHM0006702006AC39
25th January 2021

Signed: _____
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TECHNICAL REPORT



RESULTS:

Sample description:		Disposable Powder free Nitrile gloves referenced as VN-N001, colour blue	
Challenge chemical:		40% Sodium hydroxide (CAS: 1310-73-2)	
Test temperature / °C:		(23 ± 1)	
Degradation / %:		Glove 1	Glove 3
		48.6	123.9
Mean degradation (DR) / %:		-87.7	-123.9
Standard deviation (dev) / %:		37.7	
UoM ± %:		6.4	
Appearance of sample after testing:		Swollen	

Sample description:		Disposable Powder free Nitrile gloves referenced as VN-N001, colour blue	
Challenge chemical:		30% Hydrogen peroxide (CAS: 7722-84-1)	
Test temperature / °C:		(23 ± 1)	
Degradation / %:		Glove 1	Glove 2
		4.1	36.3
Mean degradation (DR) / %:		18.6	15.4
Standard deviation (dev) / %:		16.4	
UoM ± %:		7.9	
Appearance of sample after testing:		Swollen	

Sample description:		Disposable Powder free Nitrile gloves referenced as VN-N001, colour blue	
Challenge chemical:		37% Formaldehyde (CAS: 50-00-5)	
Test temperature / °C:		(23 ± 1)	
Degradation / %:		Glove 1	Glove 2
		5.8	-42.0
Mean degradation (DR) / %:		-22.0	-29.8
Standard deviation (dev) / %:		24.9	
UoM ± %:		6.9	
Appearance of sample after testing:		Swollen	

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

SATRA Technology Services (Singapore) Ltd
 SATRA Reference: CH10036070205SLC8
 Date: 29th January 2021

Signed
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