EU DECLARATION OF CONFORMITY

1)This declaration of conformity is issued under the sole responsibility of the manufacturer:

Company Name:	Zhonghong Pulin Medical Products Co.,Ltd.
Address:	West Industrial Park, Luannan County, Tangshan City, Hebei,063500, P.R.China
Product code:	ZHPFN02

2)insert description of the object of declaration

3)The object of the declaration descried in point 2 is in conformity with the relevant Union harmonisation legislation: **Personal Protective Equipment Regulation (EU) 2016/425**

4)References to the relevant harmonised standards used, including the date of the standard or references to the other technical specification, including the date of the specification, in relation to which conformity is declared:

Standards/ Technical Specifications applied	EN ISO 21420: 2020;
	EN ISO 374-1:2016+A1:2018;
	EN ISO 374-5:2016

5)Where applicable, the notified body SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777 performed the EU examination (Module B) and issued the EU type-examination certificate (Reference to that certificate)

6)Where applicable, the PPE is subject to the conformity assessment procedure (either conformity to type based on internal production control plus supervised product checks at random intervals (module C2) or conformity to type based on quality assurance of the

production process (module D under surveillance of the notified body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland Tel:+00353 (0) 1 437 2484; Notified Body Number: 2777

Signed for and on behalf of	Zhonghong Pulin Medical Products Co.,Ltd.
Date of issue	2021/4/9
Name, function	Yongmin Jia , Sales Clerk

EU Declaration of Conformity

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park, Luannan County, Tangshan City, 063500, Hebei, China
SRN: CN-MF-000001108

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
SRN: NL-AR-000000121

Product Name: Disposable medical nitrile exam glove
XS, S, M, L, XL.
GMDN Code: 56286
UMDN Code: 11882
Basic UDI: 697040580ZHPFN02XY

Classification (MDR, Annex VIII): Class I, Rule 1.
Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer. Zhonghong Pulin Medical Products Co.,Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2019, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, ISO 188:2011, ISO 21171:2006, ASTM D5250-06(2015), ASTM D5151-06(2015), ASTM D6124-06 (2017), ASTM D7160-16.
MDCG 2019-15.

Signature:

Name: Yang Yongling

Position: General Manager

Place/date Tangshan City, 2020-02-21

QUALITY MANAGEMENT SYSTEM
CERTIFICATE

Certificate No. 00121Q30150R3M/1300

We hereby certify that

Zhonghong Pulin Medical Products Co.,Ltd.

Unified Social Credit Code: 911302005661986189

Registered Address: West Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China
Production address : Pachigang Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China (Nitrile);
South of Ningtuo Village, Pachigang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
North of Lipingtuo Village, Pachigang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
South of Peituozi Village, Sigezhuang Town, Luannan County, Tangshan City, Hebei Province, P.R.China (Vinyl);
West Industrial Park, Luannan County, Tangshan City, Hebei Province, P.R.China (Nitrile)

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

GB/T 19001-2016 / ISO 9001:2015

The Quality Management System Applies in the following area:

Design, Development and Production of Nitrile and Vinyl Gloves

Certified since: January 17, 2012 Valid from: January 5, 2021 Valid until: January 7, 2024

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.
This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C001-M

Signed by: Lu Mei

Partner of IQNet

CHINA QUALITY CERTIFICATION CENTRE 中国质量认证中心

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

A 0101359

2018年版

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

Scope: Design and Development, Manufacture and Distribution of Patient Examination Gloves

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190131115 110
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH

ing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Distribution of Patient Examination Gloves
/02	c/o Minghao Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.: 190131115 110
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2059694-1

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

/03	c/o The First Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. Pachigang Industrial Park, Luannan County, Tangshan City, 063502 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves
/04	c/o The Fifth Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. South Peituozi Village, Sigezhuang Town, Luannan County, Tangshan City, 063503 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.: 190131115 110
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

...ing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Business Stream Products
Certification Department

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Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date April 13, 2021

Application for: QMS
Certificate No. : SX 2059694-1
Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2059694-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Jing Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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service@de.tuv.com
www.tuv.com/safety

Issued to:

Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park,
BDA, Luannan
Tangshan
063500 Hebei
China

Notified Body: 2777

SATRA customer number: P21110

EU Type-Examination Certificate

Certificate number: 2777/18208-02/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. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:

ZHPFN02

Description:

Disposable Powder Free Nitrile Gloves
Colour: Blue, Black

Sizes:
XS(5-6)
S(6-7)
M(7-8)
L(8-9)
XL(9-10)
XXL(10-11)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	Level	EN ISO 374-4:2019 Degradation %
(K) Sodium hydroxide 40%	6	-8.3
(P) Hydrogen peroxide 30%	2	34.1
(T) Formaldehyde 37%	4	34.3

EN ISO 374-5:2016	Level
Protection against Bacterial and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied**:**
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0309328/2109, CHT0314886/2124, CHM0309851/2110/LC/A, CHM0314155/2122/LC, CHM0309851/2110/LC, CHT0331166/2220

Signed on behalf of SATRA: Geoff Graham

Date first issued: 26/08/2021
Date of issue: 27/10/2022
Expiry date: 26/08/2026

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City
Hebei
China
063500

SATRA reference: CHT0309328 /2109

Your reference: ZHPFN02

Date of report: 23 March 2021

Samples received: 1 March 2021

Date(s) work carried out: 4-22 March 2021

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses on Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10).

Report signed by: Gladys He
Position: Technologist
Department: China Testing

Gladys He

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) were received by SATRA on 1 March 2021 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 374-2: 2019 Clause 7.2 – Air leak
EN ISO 374-2: 2019 Clause 7.3 – Water leak
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue, size: XS(5-6), S(6-7), M(7-8), L(8-9), XL(9-10) were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN ISO 374-2: 2019 Clause 7.2 – Pass
EN ISO 374-2: 2019 Clause 7.3 – Pass
EN ISO 374-5: 2016 Clause 5.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMFa

Detailed results are included on the following page(s)

Testing

Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 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	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results				UoM (See note ♣)	Result
5.1 Glove length, comfort and fit	N/A	Size	Length /mm			± 1.10 mm	N/A
			1	2	3		
		5-6	237	234	240		
		Comfortable on fit					
		6-7	230	235	236		
		Comfortable on fit					
		7-8	246	245	240		
		Comfortable on fit					
		8-9	237	235	240		
		Comfortable on fit					
		9-10	254	256	260		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		5-6	5.0				
		6-7	5.0				
		7-8	5.0				
		8-9	5.0				

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

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A	Pass
	Sample size	Leaks		
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	5-6	No leaks detected		
	6-7	No leaks detected		
	7-8	No leaks detected		
	8-9	No leaks detected		
	9-10	No leaks detected		

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 21R000882. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

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

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: blue					
Test method	**Specimen**	**Step 1 (0 kPa, 5 min)**	**Step 2 (14 kPa, 1min)**	**Step 3 (0kPa, 4min)**	**Titre of phage Phi-X174 (PFU /mL)**	**Comment**
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A210304071001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue	Gloves	-

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.
Test Method II: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement:	**3.5-9.5**

-	Unit	Result
Test Item(s)	-	**I001**
Test Method	-	**II**
Parameter	-	-
pH Value of Extracting Solution	-	5.46
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	7.4
Difference Figure	-	-
Conclusion	-	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature
Remark: Result(s) was (were) reported the average value from two trials.

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

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

Maximum Allowable Limit:	**Each of all listed PAHs: 1.0 mg/kg**

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

Test Method : With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		I001	
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 *****

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

0248

Customer details:	SATRA Technology Services (Dongguan) Ltd Unit 110, Xinzhongyin Garden Hongwei Road Xiping, Nancheng District DONGGUAN CITY Guangdong Province China 523079	SATRA reference:	CHM0309851/2110/LC/A
		Your reference:	CHT0309328
		Date of report:	28th April 2021
		Samples received:	5th March 2021
		Date(s) work carried out:	15th March to 28th April 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City
Hebei
China
063500

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue

Conditions of Issue:

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

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

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA.

All opinions and interpretations of results, and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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

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

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

Where the result corrected for uncertainty on a worst-case basis falls outside of the requirement or specification then the risk of a pass result being a false accept is up to 50%. We will therefore not provide either a pass or fail statement when this occurs but will include information in the notes in relation to the result obtained.

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

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

WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue were received on the 5th March 2021 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 ZHPFN02, 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 ZHPFN02, colour: Blue achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	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)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% Sodium hydroxide (CAS: 1310-73-2)	6
25% Ammonium hydroxide (CAS: 1336-21-6)	1
30% Hydrogen peroxide (CAS: 7722-84-1)	1
37% Formaldehyde (CAS: 50-00-0)	4

Full results are reported in the following tables.

0248

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

RESULTS AND REQUIREMENTS:

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

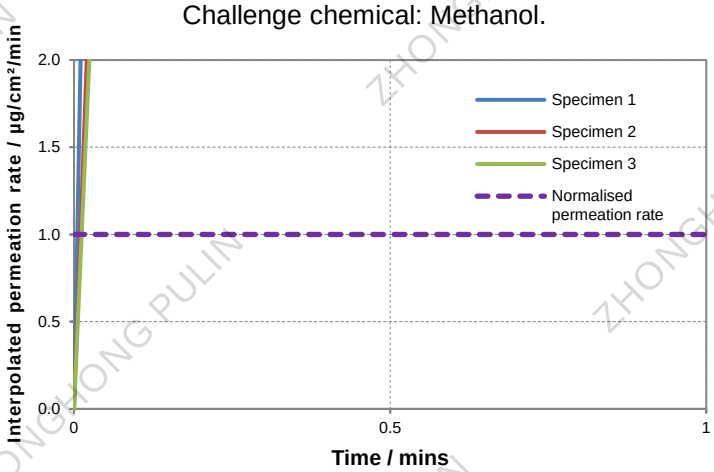
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	Test information:	Chemical:	Methanol	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)⌂	Breakthrough time (mins)▲	
	1	0.07	<1	
	2	0.07	<1	
	3	0.08	<1	
		Test result:	**<1**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

Challenge chemical: Methanol.



TECHNICAL REPORT

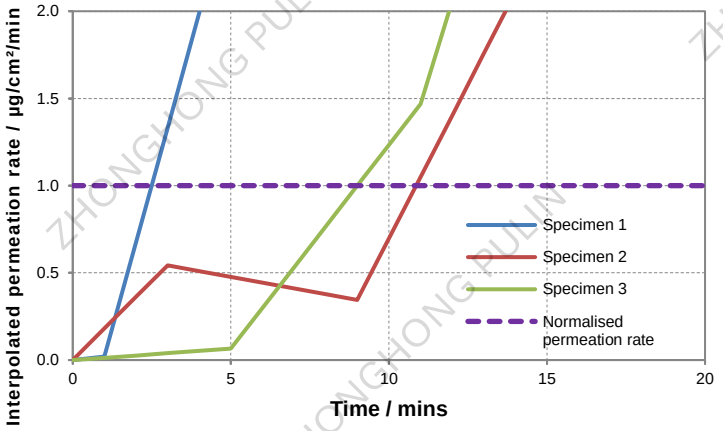
0248

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	Test information:	Chemical:	n-Heptane	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)⌂	Breakthrough time (mins)▲	
	1	0.08	2	
	2	0.08	12	
	3	0.08	9	
	4	0.11	<1	
	5	0.11	<1	
	6	0.12	>480	
		Test result:	**<1**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen		

In accordance with clauses 8.5.1.2 and 8.5.1.4, the test results were outside the defined range and required an additional 3 specimens to be tested. All 6 results have been reported and the sample was found to not meet with the minimum breakthrough time for a performance level 1 to be achieved.

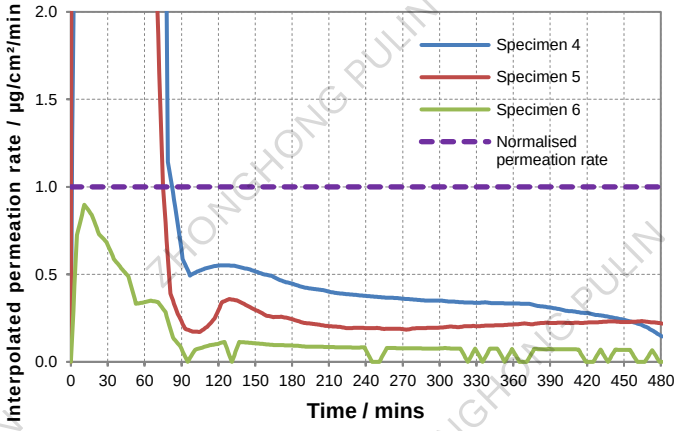
PERMEATION RATE GRAPHS

Challenge chemical: n-Heptane.



PERMEATION RATE GRAPHS

Challenge chemical: n-Heptane.



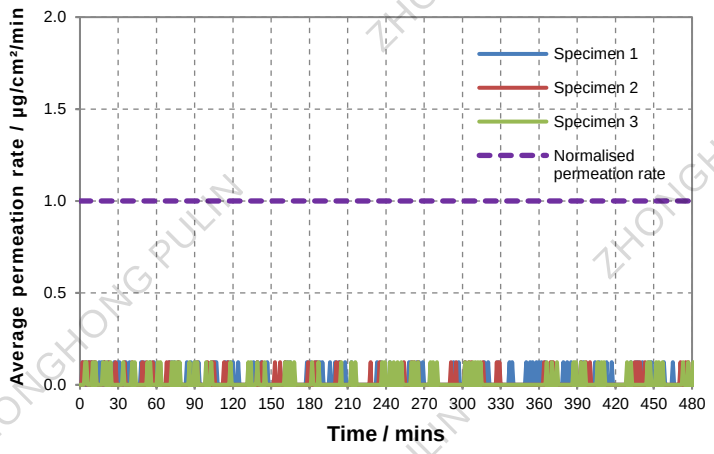
TECHNICAL REPORT

0248

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)⌂	Breakthrough time (mins)	
	1	0.08	>480	
	2	0.08	>480	
	3	0.08	>480	
		Test result:	**>480**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide .



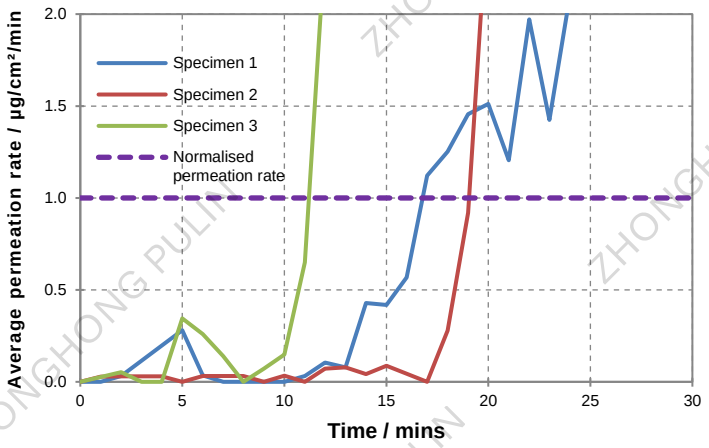
TECHNICAL REPORT

0248

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 25% Ammonium hydroxide		Level 1
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)	
	1	0.08	17	
	2	0.08	20	
	3	0.08	12	
		Test result:	**12**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

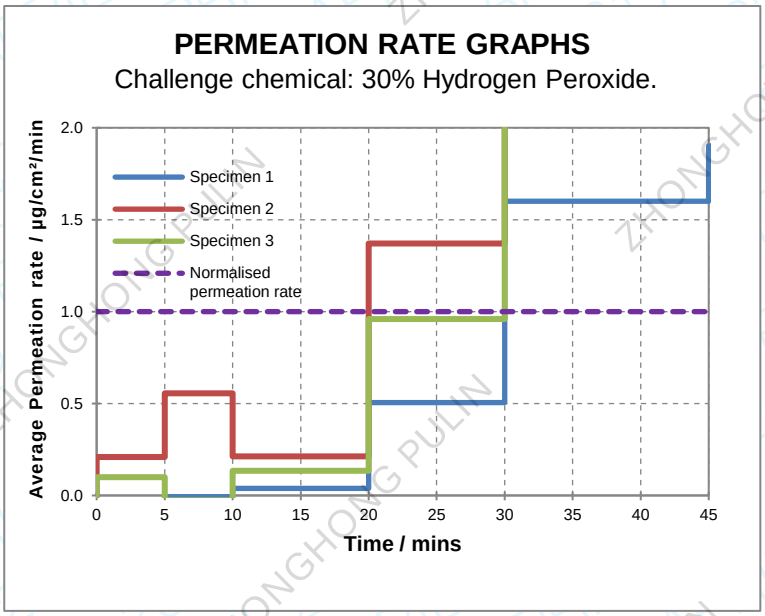
PERMEATION RATE GRAPHS

Challenge chemical: 25% Ammonium Hydroxide .



Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	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: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	1	0.08	Between 31 to 45	
	2	0.08	Between 21 to 30	
	3	0.08	Between 31 to 45	
		Test result:	Between 21 to 30	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and discoloured		

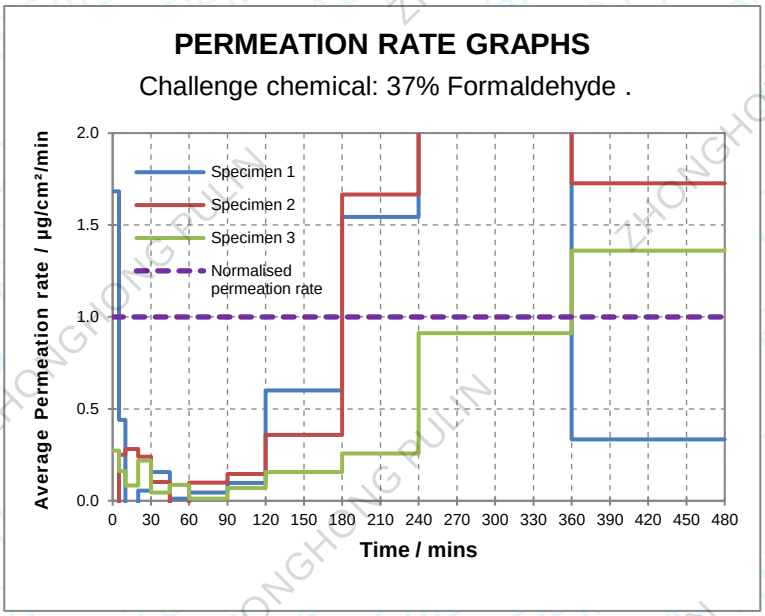
For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.



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

Test/Property	Sample reference:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 4
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	1	0.08	Between 181 to 240	
	2	0.08	Between 181 to 240	
	3	0.08	Between 361 to 480	
		Test result:	Between 181 to 240	
		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. The reading from specimen 1 after 5 minutes was considered to be an outlier and not a breakthrough.

⌂ EN 16523-1:2015+A1:2018 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 EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.

▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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0248

Customer details: SATRA Technology Services (Dongguan) Ltd
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Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0314155/2122/LC

Your reference: CHT0313568

Date of report: 15th July 2021

Samples received: 1st June 2021

Date(s) work carried out: 3rd June to 6th July 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City
Hebei
China
063500

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as ZHPFN02, colour: Blue.

Conditions of Issue:

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

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

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA.

All opinions and interpretations of results, and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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

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

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

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

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

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

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

TECHNICAL REPORT

0248

WORK REQUESTED:

Samples of gloves described as ZHPFN02, colour: Blue were received on the 1st June 2021 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 ZHPFN02, colour: Blue

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as ZHPFN02, colour: Blue achieved the following performance levels:

Chemical	Performance level
Methanol (CAS: 67-56-1)	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)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
25% Ammonium hydroxide (CAS: 1336-21-6)	1
30% Hydrogen peroxide (CAS: 7722-84-1)	2

Full results are reported in the following tables.

0248

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

RESULTS AND REQUIREMENTS:

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

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

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

TECHNICAL REPORT

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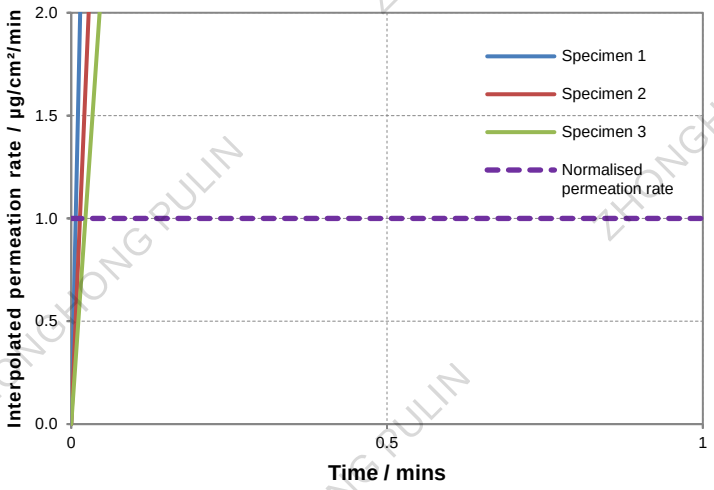
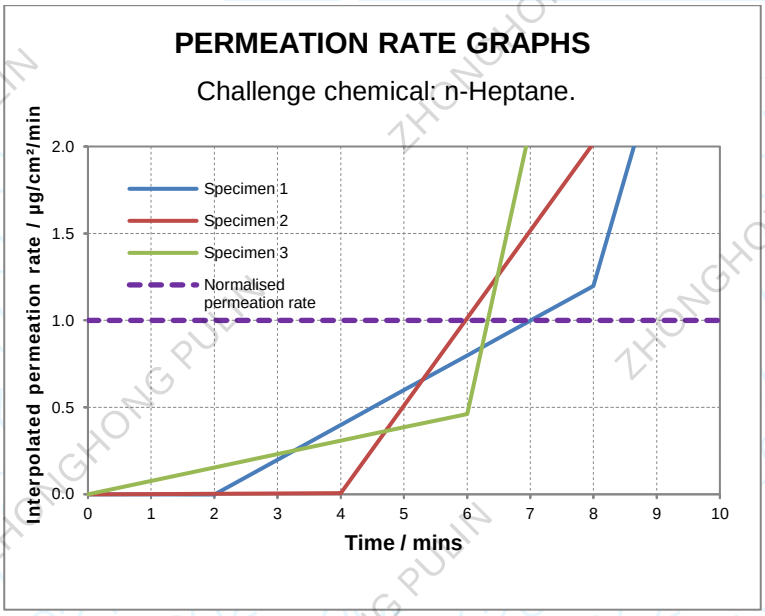
Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	**Test information:**	Chemical: Methanol		**The samples tested did not meet with the minimum breakthrough 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)⌂**	**Breakthrough time (mins)▲**	
	1	0.08	<1	
	2	0.08	<1	
	3	0.08	<1	
		Test result:	**<1**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen		

PERMEATION RATE GRAPHS

Challenge chemical: Methanol .



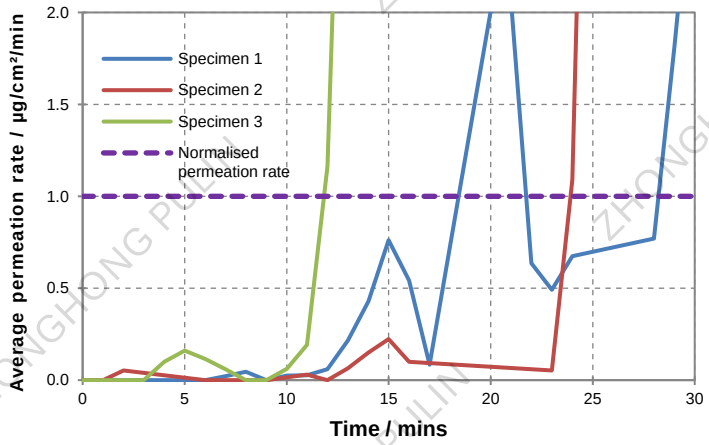
Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-005 Using stainless steel permeation cells with standardised dimensions	**Test information:**	Chemical: n-Heptane		**The samples tested did not meet with the minimum breakthrough 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)⌂**	**Breakthrough time (mins)▲**	
	1	0.07	7	
	2	0.07	5	
	3	0.07	6	
		Test result:	**5**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen		



Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	25% Ammonium hydroxide	Level 1
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Conductimetry (continuous measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	**Specimen**	**Thickness (mm)⌂**	**Breakthrough time (mins)**	
	1	0.08	19	
	2	0.08	24	
	3	0.08	12	
		Test result:	**12**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

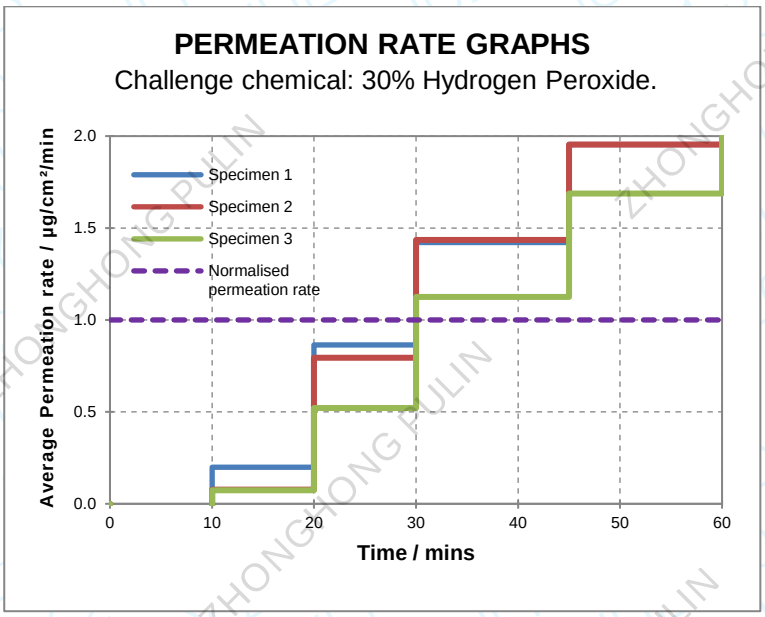
PERMEATION RATE GRAPHS

Challenge chemical: 25% Ammonium Hydroxide .



Test/Property	Sample reference:	ZHPFN02, colour: Blue		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical:	30% Hydrogen peroxide	Level 2
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Electrochemical detector (periodic measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm)⌂	Breakthrough time (mins)▼	
	1	0.07	Between 31 to 45	
	2	0.08	Between 31 to 45	
	3	0.08	Between 31 to 45	
		Test result:	Between 31 to 45	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and slightly discoloured		

For SOP CAT-025, where both the P1 and Pu 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.

⌂ EN 16523-1:2015+A1:2018 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 EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.

▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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0248

Customer details:	SATRA Technology Services (Dongguan) Ltd Unit 110, Xinzhongyin Garden Hongwei Road Xiping, Nancheng District DONGGUAN CITY Guangdong Province China 523079	SATRA reference:	CHM0309851/2110/LC
		Your reference:	CHT0309328
		Date of report:	28th April 2021
		Samples received:	5th March 2021
		Date(s) work carried out:	16th to 24th April 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County
Tangshan City
Hebei
China
063500

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue.

Conditions of Issue:

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

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

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

Where the result corrected for uncertainty on a worst-case basis falls outside of the requirement or specification then the risk of a pass result being a false accept is up to 50%. We will therefore not provide either a pass or fail statement when this occurs but will include information in the notes in relation to the result obtained.

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

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

WORK REQUESTED:

Samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue were received on the 5th March 2021 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Sample described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue achieved the following degradation results:

Chemical	Mean degradation / %
n-Heptane (CAS: 142-82-5)	49.3
30% Hydrogen peroxide (CAS: 7722-84-1)	34.1
25% Ammonium hydroxide (CAS: 1336-21-6)	41.2
40% Sodium hydroxide (CAS: 1310-73-2)	-8.3
37% Formaldehyde (CAS: 50-00-0)	34.3
Methanol (CAS: 67-56-1)	96.7

TESTING REQUIRED:

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

RESULTS:

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	n-Heptane (CAS: 142-82-5)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	47.8	54.1	46.1
Mean degradation (DR) / %:	49.3		
Standard deviation (σ_{DR}) / %:	4.2		
UoM / ± %:	14.2		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	21.9	37.1	43.3
Mean degradation (DR) / %:	34.1		
Standard deviation (σ_{DR}) / %:	11.0		
UoM / ± %:	12.1		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	25% Ammonium hydroxide (CAS: 1336-21-6)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	48.0	56.6	18.8
Mean degradation (DR) / %:	41.2		
Standard deviation (σ_{DR}) / %:	19.8		
UoM / ± %:	13.1		
Appearance of samples after testing:	Swollen and discoloured		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-9.4	20.4	-35.9
Mean degradation (DR) / %:	-8.3		
Standard deviation (σ_{DR}) / %:	28.2		
UoM / ± %:	9.9		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	40.0	45.6	17.3
Mean degradation (DR) / %:	34.3		
Standard deviation (σ_{DR}) / %:	15.0		
UoM / ± %:	12.2		
Appearance of samples after testing:	Swollen		

Sample description:	Disposable Powder Free Nitrile Gloves referenced as ZHPFN02, colour: Blue		
Challenge chemical:	Methanol (CAS: 67-56-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	98.5	96.9	94.5
Mean degradation (DR) / %:	96.7		
Standard deviation (σ_{DR}) / %:	2.0		
UoM / ± %:	See below*		
Appearance of samples after testing:	Swollen		

*As a result of the low force required to puncture the specimen after degradation, this result is close to being outside the normal operating range of the tensile testing machine, hence that force is subject to a significant measurement uncertainty. However, this does not affect the overall result of the test as the degradation result for the specimen against the challenge chemical was very high.

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

Test Report No. 7191244410-EEC20/02-LDY
dated 12 Oct 2020

PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 11 Sep 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

11 Sep 2020 to 07 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand /Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Z/Z	Blue	20200927	XS	400	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation

PSB Singapore

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size XS: ≤ 80	13	78	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is not dressed with talcum powder, based on client's declaration letter on 21 Sep 2020	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.08 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

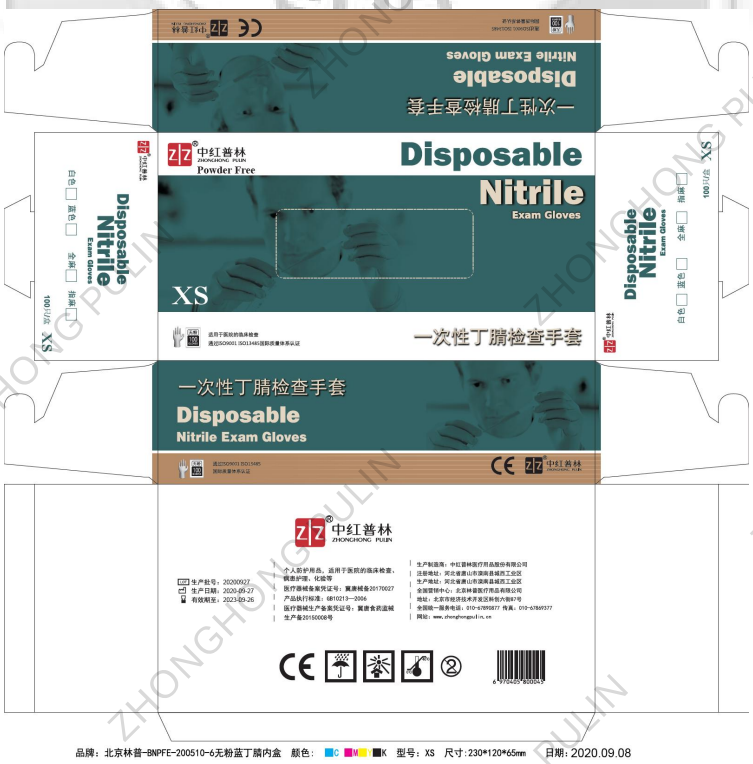

Photo 2: Packaging artwork for Nitrile Disposable Exam Gloves, Z/Z, Lot No. 20200927, Blue, Size XS

PSB Singapore

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Effective 01 September 2020

Test Report No. 7191240823-EEC20/01-LDY
dated 20 Oct 2020

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

SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	S	400	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
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https://www.tuvsud.com/en-sg
Co. Reg : 199002667R

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

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size S

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	246	Passed
	b) Width (mm)	For Size S: 80 ± 10	13	83	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.6	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size S

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.52 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

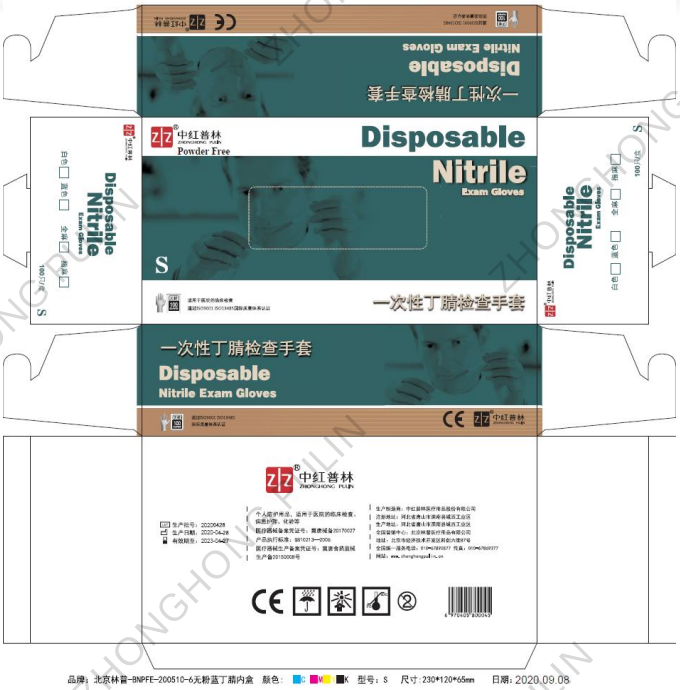

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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Effective 01 September 2020

Test Report No. 7191240823-EEC20/02-LDY
dated 20 Oct 2020

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	M	400	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	3	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	245	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	93	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.9	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size M

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	1.08 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

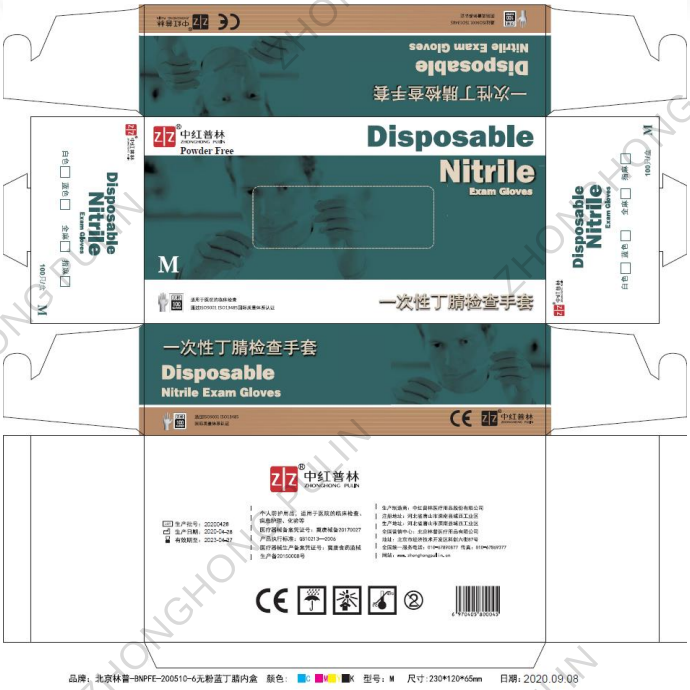

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	L	399	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

TÜV SÜD PSB

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https://www.tuvsud.com/en-sg
Co. Reg : 199002667R

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

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size L

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	3	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	243	Passed
	b) Width (mm)	For Size L: 110 ± 10	13	104	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.5	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	8.1	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size L

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.96 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

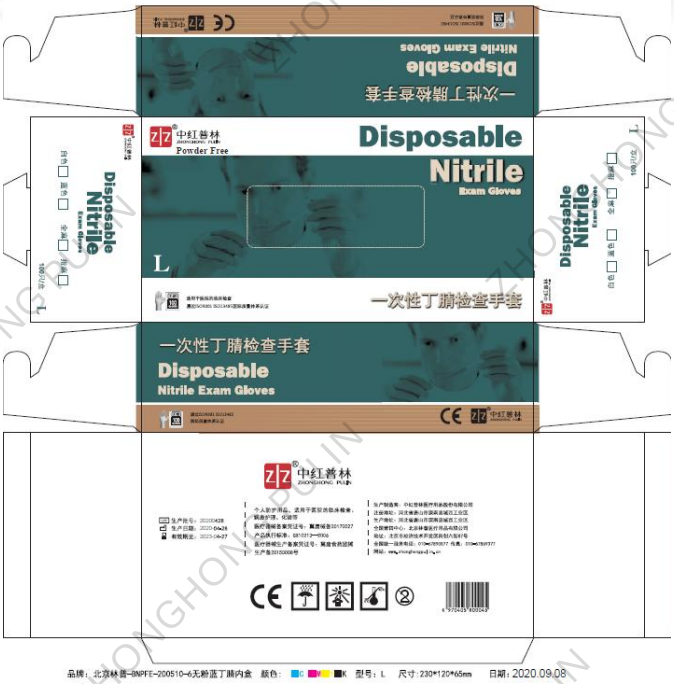

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Zhonghong Pulin Medical Products Co.,Ltd. on 21 Jul 2020.

TESTED FOR:

Zhonghong Pulin Medical Products Co.,Ltd.
West Industrial Park,
Luannan County,
Tangshan City, China

TEST DATE:

22 Jul 2020 to 14 Aug 2020, 20 Oct 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Nitrile Disposable Exam Gloves	Blue	20200428	XL	401	Zhonghong Pulin Medical Products Co.,Ltd.

Lot size as specified by client: 150,001 to 500,000 pieces

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

2. EN 455-2:2015 Medical gloves for single use
   Part 2: Requirements and testing for physical properties

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves
   - Clause 4.6 Labelling

RESULTS:

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size XL

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	2	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	249	Passed
	b) Width (mm)	For Size XL: ≥ 110	13	114	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue, Size XL

Table 4: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.64 mg per glove	Passed

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
		Inferred results	Passed

PSB Singapore

REMARKS:

1. Labelling requirements are assessed based on submitted packaging artwork by client on 20 Oct 2020.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Lee Dai Yi
Engineer
Medical Health Services (NAM)

APPENDIX:

Photo 1: Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

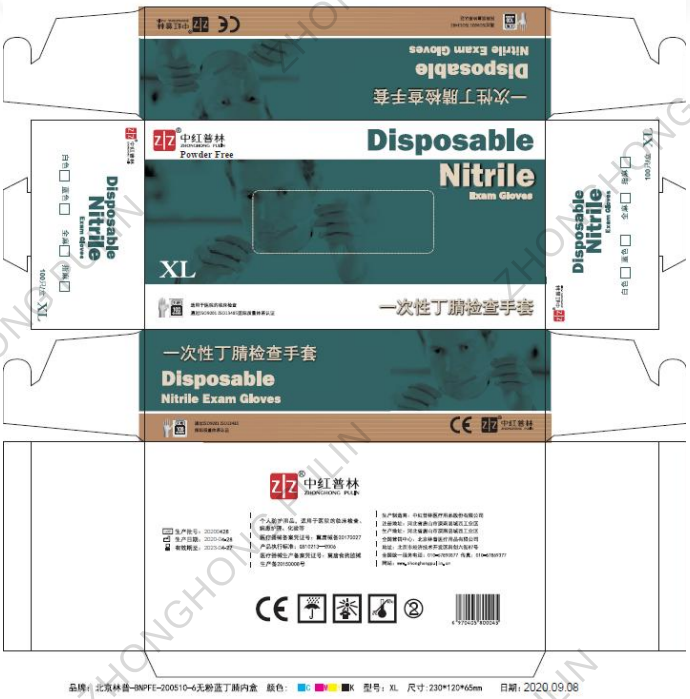

Photo 2: Packaging Artwork for Nitrile Disposable Exam Gloves, Lot No. 20200428, Blue

PSB Singapore

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Effective 01 September 2020

SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Zhonghong Pulin Medical Products Co., Ltd.**
CLIENT ADDRESS	West Industrial Park, BDA, Luannan, Tangshan, 063500 Hebie, P.R. China
TEST PERIOD	29-Jan-2022~16-Feb-2022
RESULT SUMMARY	The tested items **complied with** European Resolution Res AP (2004) 4 on rubber products intended to come into contact with foodstuffs. - Specific Migration of Acrylonitrile **PASS** - 1,3 - Butadiene content **PASS**

Prepared By	**Authorized By**
Wei Jun	Liu
(Wei Jun) Report Drafter	(Leo Liu) Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

RECEIPT DATE / TEST DATE

29-Jan-2022/ 29-Jan-2022

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Powder free nitrile glove,blue
Sample Specification: M
Batch No./Date: 2022.1.25
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721670365	Blue glove	

TEST RESULT(S)

Note: The migration results in this report were tested and expressed based on single use articles.

1. Specific migration of Acrylonitrile
   - Test method: With reference to BS EN 13130-3:2004
   - Migration ratio(S/V): 6dm^2/L
   - Test condition: 3% Acetic acid, 40°C for 30 minutes

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Acrylonitrile	<0.01	0.01

- Test condition: 10% Ethanol, 40°C for 30 minutes

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Acrylonitrile	<0.01	0.01

- Test condition: 95% Ethanol, 40°C for 30 minutes

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Acrylonitrile	<0.01	0.01

- Test condition: Iso-octane, 20°C for 6 minutes

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
Acrylonitrile	<0.01	0.01

2. 1,3 - Butadiene content
   - Test method: With reference to BS EN 13130-4:2004

Test Item(s)	Result(s) [mg/kg]	Maximum Permissible Limit [mg/kg]
1,3 - Butadiene	<0.1	1

Note: This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-