

Guanti medicali in nitrile

elasticizzati/senza polvere/idonei al contatto con alimenti

DOCUMENTAZIONE

Guanti medicali in nitrile elasticizzati/senza polvere



Conf. 100 pezzi

Idonei al contatto per alimenti
monouso / non-sterile

Guanti medicali in nitrile elasticizzati/senza polvere

CARATTERISTICHE

Guanti monouso in nitrile di colore blu chiaro, non sterili, senza polvere, 100% latex-free. Ambidestri con polsino salva strappo, sono dotati di superficie microruvida che garantisce la massima sensibilità ed una capacità di presa ottimizzata. Validi per l'uso a contatto con gli alimenti ai sensi del Reg. UE 10/2011, Reg. 1935/2004/CE e DM 21.03.1973 s.m.i.

DETTAGLI TECNICI

Nitrile: colore BLU chiaro

Polsino: dotato di elastico

Linea prodotto: LyncMed

Tipo: senza polvere / monouso / non sterile

Confezionamento: box da 100 pezzi

Imballo: 1000 pezzi

Standard: Dispositivo di protezione individuale di I categoria - livello di protezione B

- **UNI EN 455-1:2015:** assenza di fori
- **UNI EN 455-2:2015:** proprietà fisiche conformi a normativa
- **UNI EN 455-3:2015:** valutazione biologiche conformi a normativa
- **UNI EN ISO 21420:2020**
- **EN ISO 374-1:2016 / Type B, EN 374-2:2014, EN 374-4:2013, EN ISO 374-5:2016:** protezione da microorganismi
- **EN ISO 16523-1:2015:** resistenza alla permeazione di prodotti chimici
- **EN 420:2003+A1:2009:** conforme ai requisiti generali e metodi di prova

Standard: Dispositivo medico di classe I, ad uso temporaneo in relazione agli orifizi del corpo, ai sensi reg. 5 allegato VIII del regolamento UE 2017/425.

CND T01020204 (Guanti non chirurgici in nitrile)

Progressivo di registrazione dispositivo medico: N° 2025597 (taglia S), n° 2027928 (taglia M), 201391, n° 2027929 (taglia L), n° 2027930 (taglia XL)

Per alimenti ai sensi Reg. UE 10/2011, Reg. 1935/2004/CE e DM 21.03.1973 s.m.i. (EN 1186-1:2002, EN 1186-9:2002, EN 1186-14:2002).

Condizioni di conservazione: Conservare i guanti nel loro imballaggio originale in luogo fresco e asciutto. Evitare l'esposizione diretta alla luce del sole, all'ozono ed a fonti di calore. Effettuare sempre una prova preliminare nelle reali condizioni di utilizzo. Non utilizzare i guanti in contatto con prodotti chimici non testati o con prodotti irritanti e corrosivi. Indossare i guanti con le mani asciutte e pulite.

Shelf life: 5 anni dalla produzione

Taglie disponibili: S - M - L - XL

FUNZIONI

Protegge da agenti biologici e da contatto accidentale con sostanze chimiche, ideale per esame, terapia, diagnostica, uso domestico, per la manipolazione di alimenti, catering, estetica, pulizia e igiene, hobbistica, laboratori, settore medico-veterinario.

Guanti medicali in nitrile elasticizzati/senza polvere

ISTRUZIONI PER L'USO

Prima dell'impiego, ispezionare i guanti per individuare eventuali difetti o imperfezioni. Utilizzare i guanti con mani asciutte, pulite e prive di anelli. Per agevolare la calzatura del guanto effettuare una presa ampia sul polsino con l'altra mano, evitando l'esercizio di un'eccessiva trazione che potrebbe causare la rottura del guanto. Prima e dopo aver indossato il guanto controllare attentamente l'integrità e verificare l'assenza di fori, lacerazioni o difetti visibili. Nel caso si riscontrino eventuali difettosità, sostituire il guanto danneggiato. Non utilizzare i guanti oltre il tempo di impiego previsto dagli indici di protezione sotto riportati per le diverse categorie di prodotti chimici. Il prodotto è monouso, non riutilizzare.

TASSI DI PERMEAZIONE

SOSTANZA CHIMICA	LIVELLO	SOSTANZA CHIMICA	LIVELLO
N-eptano	J 0	Idrossido di sodio sol. 40%	K 0
Perossido di Idrogeno 30%	P 2	Formaldeide sol. 37%	T 5
Idrossido di Ammonio sol. 25%	O 0		

Legenda classe di permeazione:

Livello 0: tempo di passaggio < 10 minuti

Livello 1: tempo di passaggio > 10 minuti

Livello 2: tempo di passaggio > 30 minuti

Livello 3: tempo di passaggio > 60 minuti

Livello 4: tempo di passaggio > 120 minuti

Livello 5: tempo di passaggio > 240 minuti

Livello 6: tempo di passaggio > 480 minuti

AVVERTENZE

- La scelta del guanto deve essere effettuata conoscendo l'attività lavorativa ed il processo di lavorazione eseguito dall'operatore, tenendo conto delle condizioni di lavoro e i rischi connessi.
- Al termine dell'utilizzo, sfilare il guanto rovesciandolo, al fine di minimizzare il rischio di contaminazione microbica, procedendo alla smaltizione in base alle linee guida della struttura di appartenenza o secondo le indicazioni dell'ente locale.



E' un dispositivo medico.
Leggere le avvertenze e le istruzioni per l'uso.
Autorizzazione del 15/11/2020

Box 100 pz. Taglia S



Box 100 pz. Taglia M



Box 100 pz. Taglia L



Box 100 pz. Taglia XL



Certificazioni / Test report





[Stampa](#)

[Scarica il dataset](#)

Elenco dei dispositivi medici

Criteri di ricerca:
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM:
Codice attribuito dal fabbricante: **20139**
Nome commerciale e modello:
Classificazione CND: **T01020204**
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

Elenco dispositivi individuati

Dati aggiornati al:07/03/2021

DISPOSITIVO MEDICO/ASSEMBLATO							FABBRICANTE/ASSEMBLATORE						
TIPOLOGIA	IDENTIFICATIVO		CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE	NOME COMMERCIALE E MODELLO	CND	CLASSE	DATA FINE		RUOLO AZIENDA	DENOMINAZIONE	CODICE FISCALE	PARTITA IVA/VAT NUMBER	NAZIONE
DISPOSITIVO	DI	ISCRITTO AL REPERTORIO					PRIMA PUBBLICAZIONE	IMMISSIONE IN COMMERCIO					
Dispositivo	2025597	S	201390	LM	T01020204 - GUANTI NON CHIRURGICI IN NITRILE	I - Classe I non sterile e senza funzioni di misura	15/11/2020		FABBRICANTE	LYNCMED TECHNOLOGY S.R.L.	10331280965	10331280965	IT
Dispositivo	2027928	S	201391	LM	T01020204 - GUANTI NON CHIRURGICI IN NITRILE	I - Classe I non sterile e senza funzioni di misura	15/11/2020		FABBRICANTE	LYNCMED TECHNOLOGY S.R.L.	10331280965	10331280965	IT
Dispositivo	2027929	S	201392	LM	T01020204 - GUANTI NON CHIRURGICI IN NITRILE	I - Classe I non sterile e senza funzioni di misura	15/11/2020		FABBRICANTE	LYNCMED TECHNOLOGY S.R.L.	10331280965	10331280965	IT
Dispositivo	2027930	S	201393	LM	T01020204 - GUANTI NON CHIRURGICI IN NITRILE	I - Classe I non sterile e senza funzioni di misura	15/11/2020		FABBRICANTE	LYNCMED TECHNOLOGY S.R.L.	10331280965	10331280965	IT

Certificate No.: 2020LM191109

EC DECLARATION OF CONFORMITY

According to MDR2017/745

We

Lyncmed Medical Technology (Beijing) Co., Ltd
Room 119, Floor 1 GUOTOUSHANGKE Building No.1111, South Huihe Road, ChaoYang
District, 100022 Beijing, China
Tel: +86-10-86468058

Declare under our sole responsibility that the products:

1. Non-sterile Examination Latex gloves, Class I;
2. Nitrile Examination Gloves, Class I;
3. Vinyl Examination Gloves, Class I;

are produced in conformity with the technical documentation of Annex II and III meets the provisions of the Medical Device Regulation 2017/745 which apply to them.

The products are produced according to the following harmonized standards:

EN 455-1:2000 Medical gloves for single use Part 1: Requirements and testing for freedom from holes

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

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

This declaration is valid for the above mentioned product with the CE-Mark.

European Authorized Representative:

Lyncmed Technology SRL

Add: Corso Buenos Aires 77/A, 20124, Milano (MI), Italy

Contact: Tina Tian

Tel/Fax: +86-15011563730

mail: TinaTian@lyncmed.com

Place: Beijing, China

Date: 4 Dec. 2020

Name: 王鹏

Position: CEO

Signature:



LyncMed Technology International Ltd



scan to see the report



QDHL2009009945MD

Test Report

Report No.: QDHL2009009945MD

Sample Description: NITRILE EXAMINATION GLOVES

Applicant: LYNCMED MEDICAL TECHNOLOGY
(BEIJING) CO., LTD.

Test Type: SUBMITTED BY CLIENT

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

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Sample Photo



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
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Report No.: QDHL2009009945MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test	/	EN455-1: 2020	Sample quantity: 200 AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass

End of Report

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

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[illegible]100 Center Street, Suite 500, Boston, MA 02108 • Tel: 617-552-3300 • www.sagepub.com • sage@china.sagepub.com

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statement

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5. Should you have any queries or objection to the test report, please contact us within 15 days after receiving the report.

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Tel: 0532-68999187

Zip: 266101

Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

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Test Report

No. SHAHG1826661102 A01

Date: 07 Dec 2018

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LYNOMED MEDICAL TECHNOLOGY(BEIJING) CO., LTD

ROOM 119, FLOOR 1, GUOTOUSHANGKE BUILDING NO.1111, SOUTH HUIHE ROAD CHAOYANG DISTRICT, CHINA

THIS REPORT IS TO SUPERSEDE TEST REPORT NO.SHAHG1826661101, DATE:2018/12/06.

The following sample(s) was/were submitted and identified on behalf of the clients as : NITRILE GLOVE

SGS Job No. : SHHL1811067545CW - SH

Style No. : S, M, L, XL

Date of Sample Received : 29 Nov 2018

Testing Period : 29 Nov 2018 - 06 Dec 2018

Test Requested : Selected test(s) as requested by client.

Test Method : Please refer to next page(s).

Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Overall migration	PASS
French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Peroxide value	PASS
French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Volatile organic matter (VOM)	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Jenny Yao

Jenny Yao
Approved Signatory



SHAHG1826661102 A01



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Test Report

No. SHAHG1826661102_A01

Date: 07 Dec 2018

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	SHA18-266611.001	Blue rubber glove (XL)	Nitrile rubber

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C = degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and EN 1186-1:2002 for selection of test methods;
EN1186-9:2002 aqueous food simulants by article filling method;
EN 1186-14:2002 substitute test

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Overall migration	Conclusion
10% Ethanol (V/V) aqueous solution	2.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²	PASS
20% Ethanol (V/V) Aqueous Solution	2.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²	PASS
50% Ethanol (V/V) aqueous solution	2.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²	PASS
95% Ethanol	2.0hr(s)	40°C	10mg/dm ²	8.2mg/dm ²	PASS
Isooctane	0.5hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²	PASS

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm² or 12mg/kg.
- (2) Analytical tolerance of fatty food simulants is 3 mg/dm² or 20mg/kg.
- (3) Test condition & simulant were specified by client.

French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Peroxide value



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 中国·上海·徐汇区宜山路889号3号楼 邮编: 200230 (H&E: 86-21) 61402554 (H&E: 86-21) 61159868 s-gs.china@sgs.com

Test Report

No. SHAHG1828661102_A01

Date: 07 Dec 2018

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Test Method : With reference to European pharmacopoeia, 2005 Appendix X F. Peroxide Value method A.

Test Item(s)	Limit	Q01
Peroxide Value	★	Absent
Conclusion		PASS

Notes:

(1) ★ = Absent.

French Arrêté du 9 November 1994, French Décret 2007-766 with amendments, DGCCRF Methodological Sheet "File organic materials – synthetic matter" -Volatile organic matter (VOM)

Test Method : With reference to French Arrêté du November 1992 Annex III.

Test Item(s)	Limit	Unit	MDL	Q01
Volatile organic matter (VOM)	0.50	% (w/w)	0.10	0.12
Conclusion				PASS



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Test Report

No. SHAHG1826661102 A01

Date: 07 Dec 2018

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Sample photo:



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*** End of Report ***



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TEST REPORT

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3F, Building Block 2, No. 3400 Gonghexin Road,
Jing'an District - Shanghai 200436, P.R. CHINA
上海市静安区共和新路3400号2幢3层
Tél. : +86 21 68 55 50 32
Fax : +86 21 68 55 50 33
E-mail : ctcshanghai@ctcgroupe.com

Report No.: S200909071_2

28 October 2020

naomizhou@lyncmed.com

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

ROOM1601, BUILDING NO. 2, ZHUBANG 2000
BUSINESS BUILDING, BALIZHUANG XILI99
CHAOYANG DISTRICT
100022 BEIJING
CHINA

Date of receipt : 07 Sept. 2020
Testing period : 10 Sept. 2020
: 11 Sept. 2020

Buyer: —

Sample description: Disposable nitrile gloves

Test(s) requested : —

Service : REGULAR

Brand / Section : —

Season : —

End use : —

Factory name : —

Factory code : —

For CE Marking : Yes

Previous report : —

Product category : —

Product type : —

Test stage : FIRST TEST

Supplier name : —

Exported to : —

1. Conclusion:

	Tests description	Conformity
	EN ISO 374-1	
1	Air Leak Test	Pass
2	Water Leak Test	Pass

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

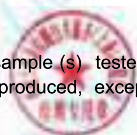
Approved by

Henry YAN
Laboratory Manager

This test report in version S200909071_2 supersedes the report S200909071_1

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To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.





TEST REPORT

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Report No.: S200909071_2

28 October 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

2. Sample(s) description assigned by laboratory:

<u>Size</u>	<u>Analyzed product</u>	<u>Description</u>	<u>Sample information</u>
	GLOVE	Whole glove	

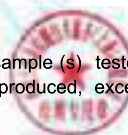


200909071

This test report in version S200909071_2 supersedes the report S200909071_1

The report is issued by CTC Shanghai under its General Conditions printed overleaf. The results shown in this report refer only to the sample(s) tested. Except by special arrangement, the test items will not be retained by CTC Shanghai for more than 3 months. The test report shall not be reproduced, except in full, without the written approval of the testing laboratory.

To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.





TEST REPORT

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Report No.: S200909071_2

28 October 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Air Leak Test	EN 374-2:2019				Pass
Glove thickness			mm	0.10	
Air pressure used to test			kPa	3.5	
Result		No air bubbles		No air bubbles	
5.2. Water Leak Test	EN 374-2:2019				Pass
Result		No water leak		No water leak	

END OF TEST REPORT

: The test was carried out by external accredited laboratory, not within their accreditation scope.

This test report in version S200909071_2 supersedes the report S200909071_1

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To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.





SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinz hongyin Garden, Xipin
Nancheng District, Dongguan City
Guangdong Province, China
Tel: + 86 (0) 769 2288802
email: info@satrafe.com

Customer details: LyncMed Medical Technology (Beijing)
Co., Ltd
Room 1601, Building No.2, Zhubang 2000
Business Building, ChaoYang District
100022 Beijing
China

SATRA reference: CHT0302891 /2039

Your reference: Disposable nitrile
gloves

Date of report: 24 October 2020

Samples received: 24 September 2020

Date(s) work 25 September to 24
carried out: October 2020

TECHNICAL REPORT

Subject: EN ISO 374-5: 2016 clause 5.3 - Viruses tests for Disposable nitrile gloves, Blue,
powder-free, size L/.

Conditions of Issue

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

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

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

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

Report signed by: Adam Zhang
Position: Technologist
Department: China Testing

WORK REQUESTED

Samples described as Disposable nitrile gloves, Blue, powder-free, size L/ were received by SATRA on 24 September 2020 for testing in accordance with EN ISO 374-5: 2016.

SAMPLE SUBMITTED**TESTING REQUESTED**

EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)

CONCLUSION

The samples described as Disposable nitrile gloves, Blue, powder-free, size L/ were found to achieve the following results:

EN ISO 374-5: 2016 Clause 5.3 – Pass

Detailed results are included on the following page(s)

Protection Against Virus Test Results

Testing was conducted at a third-party laboratory and reported under their reference 20R006342. 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 nitrile gloves, Blue, powder-free, size L/						
Test method	Specimen	Step 1 (0 kPa, 5 min)	Step 2 (1 kPa, 1min)	Step 3 (0kPa, 4min)	Titre of phage Phi-X 1 (PFU /mL)	Comment
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	NA
	- control	No penetration	No penetration	No penetration	<	NA
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	<	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	<	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	<	Pass

***** End of Report *****



TECHNICAL REPORT

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

1. GENERAL

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

2. FEES AND PAYMENT

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

3. INTELLECTUAL PROPERTY RIGHTS

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

4. SUSPENSION OR TERMINATION OF SERVICES

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

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for
 - 5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
 - 5.2.2 fraud or fraudulent misrepresentation; or
 - 5.2.3 any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6. MISCELLANEOUS

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

7. CONFIDENTIALITY

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

8. AMENDMENT

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

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.
- 9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.



TECHNICAL REPORT

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

1 PROVISION OF SERVICES

- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.
- Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

1 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

1 RISK/TITLE OF GOODS

- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- 13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- 13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- 13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- 13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

- 13.4 Until ownership of Goods has passed to the Client, the Client shall:

- 13.4.1 hold the Goods as SATRA's bailee
- 13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- 13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- 13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- 13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- 13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- 13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

- 13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause shall remain in effect.

1 PATENTS

- 14.1 SATRA gives no indemnity against any claim of infringement of any Patent. Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order

15 WARRANTY OF GOODS

- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

1 DEFECTIVE GOODS

- 16.1 Subject to clauses 16.6 and 16.7 if:

- 16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- 16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and
- 16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises

- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

- 16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- 16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- 16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- 16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

- 16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

- 16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

TEST REPORT



中国认可
国际互认
检测
TESTING
CNAS L4577

Page 1/4

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Report No.: S200808753_1

02 September 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

ROOM1601, BUILDING NO. 2, ZHUBANG 2000
BUSINESS BUILDING, BALIZHUANG XILI99
CHAOYANG DISTRICT
100022 BEIJING
CHINA

Date of receipt : 28 Aug. 2020
Testing period : 01 Sept. 2020
: 02 Sept. 2020

Buyer: —

Sample description: Disposable nitrile gloves

Test(s) requested : —
Service : REGULAR
Brand / Section : —
Season : —
End use : —
Factory name : —
Factory code : —

For CE Marking : Yes

Previous report : —
Product category : —
Product type : —
Test stage : FIRST TEST
Supplier name : —
Exported to : —

1. Conclusion:

	Tests description	Conformity
	EN ISO 21420	
1	pH - Textile (KCl solution)	Pass
2	Polycyclic Aromatic Hydrocarbons (8)	Pass
3	Dexterity	Level 5

Pass: requirements met Fail: requirements not met None: no requirement for this test N/A: not applicable

Approved by

Henry YAN
Laboratory Manager

Yvonne MAO
Senior Analytical Chemical Engineer

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To declare the conformity to the requirement, the uncertainty of measurement, associated to the test results, has not been taken into account.



TEST REPORT



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CNAS L4577

Page 2/4

Report No.: S200808753_1

02 September 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

2. Sample(s) description assigned by laboratory:

Size	Analyzed product	Description	Sample information
	GLOVE	Whole glove blue nitrile palm	



200808753

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TEST REPORT



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Page 3/4

Report No.: S200808753_1

02 September 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO.,LTD (C41517)

3. GLOVE/

Whole glove

	Method	Client Requirement	Unit	Result	Conformity
5.2. Dexterity	EN ISO 21420: 2020				
Smallest diameter of pin fulfilling test condition			mm	5.0	
Smallest diameter of pin fulfilling test condition (2)			mm	5.0	
Smallest diameter of pin fulfilling test condition (3)			mm	5.0	
Smallest diameter of pin fulfilling test condition (4)			mm	5.0	
Performance level				5	

blue nitrilel palm

	Method	Client Requirement	Unit	Result	Conformity
(+) 4.2. pH - Textile (KCl solution)	ISO 3071:2020				Pass
pH value		3.5< - <9.5		7.7	
▲ 4.2. Polycyclic Aromatic Hydrocarbons (8)	ISO/TS 16190: 2013				Pass
Benzo(a)anthracene		<1	mg/kg	<0.1	
Chrysene		<1	mg/kg	<0.1	
Benzo(b)fluoranthene		<1	mg/kg	<0.1	
Benzo(k)fluoranthene		<1	mg/kg	<0.1	
Benzo(a)pyrene		<1	mg/kg	<0.1	
Dibenzo(a,h)anthracene		<1	mg/kg	<0.1	
Benzo(e)pyrene		<1	mg/kg	<0.1	
Benzo(j)fluoranthene		<1	mg/kg	<0.1	

END OF TEST REPORT

(+)CNAS accreditation

▲: The test was carried out by external accredited laboratory under their accreditation scope.

Table of Performance Level for Glove

Test Item	Performance Level					
	0 ^{###}	1	2	3	4	5

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Report No.: S200808753_1

02 September 2020

APPLICANT: LYNCMED MEDICAL TECHNOLOGY (BEIJING)
CO., LTD (C41517)

Finger dexterity (EN ISO 21420) Smallest diameter of pin fulfilling test conditions (mm)	---	11.0	9.5	8.0	6.5	5.0
--	-----	------	-----	-----	-----	-----

Performance level 0 means the glove falls below the minimum performance level for the given individual hazard

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TEST REPORT

Report No. : CH:TX:1042003821

DATE : 25/01/2019



SHHL1811067691SD

LYNCMED MEDICAL TECHNICAL(BEIJING)CO.LTD
 ROOM 119, FLOOR 1, GUOTOUSHANGKE BUILDING NO 111, SOUTH HUIHE R
 CHINA
 A/C F819301 SGS-CSTC STANDARDS TECHNICAL SERVICES (SHANGHAI) CO., LTD.
 CONTACT PERSON :

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :
 SAMPLE DESCRIPTION

GLOVES
 NITRILE GLOVE
 M

STYLE NO.
 PHOTO APPENDIX.



SAMPLE RECD ON

22/01/2019

TESTING PERIOD : 22/01/2019 – 25/01/2019

Summary of Test Results/Conclusion

Test Method / Standard	Clause/Test Name	Status / Performance Level
EN 374-2:2014	Protective gloves against chemicals and micro-organisms: Determination of resistance penetration	
	Clause 4.1 – Air leak test	Pass
	Clause 4.2 – Water leak test	Pass
EN 16523-1:2015	Permeation by Liquid chemical under conditions of continuous contact.	
	Methanol	Level - 0
EN 374-4:2013	Resistance to Degradation by Chemicals	
	Methanol	Refer results

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K. PACHAIYAPPAN
 ASST. MANAGER

Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

TEST REPORT

Report No. : CH:TX:1042003821

DATE : 25/01/2019



SHHL18110875918D

RESULTS

EN 374-2 : 2014 Protective gloves against chemicals and micro-organisms – Part-2: Determination of resistance penetration

Clause	Test Name	Test Results		Performance level
4.1	Air leak Test (Air Pressure Used : 0.5 kPa)	Specimen #	Leakage	Pass
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	
4.2	Water leak test	Specimen #	Leakage	Pass
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	
		Size M	No Leakage	

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

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR $1.0 \mu\text{g cm}^{-2}$ min^{-1} (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Methanol 67-56-1	Open loop/ Nitrogen	Continuous measurement With GC-FID	0.06 0.05 0.06	<1 <1 <1	Level - 0	Severe swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.

Part 1: Terminology and performance requirements for chemical risks.

Table 1: Permeation performance levels.

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

Performance levels are based on the lowest individual results achieved per chemical

**** End of page****

TEST REPORT

Report No. : CH:TX:1042003821

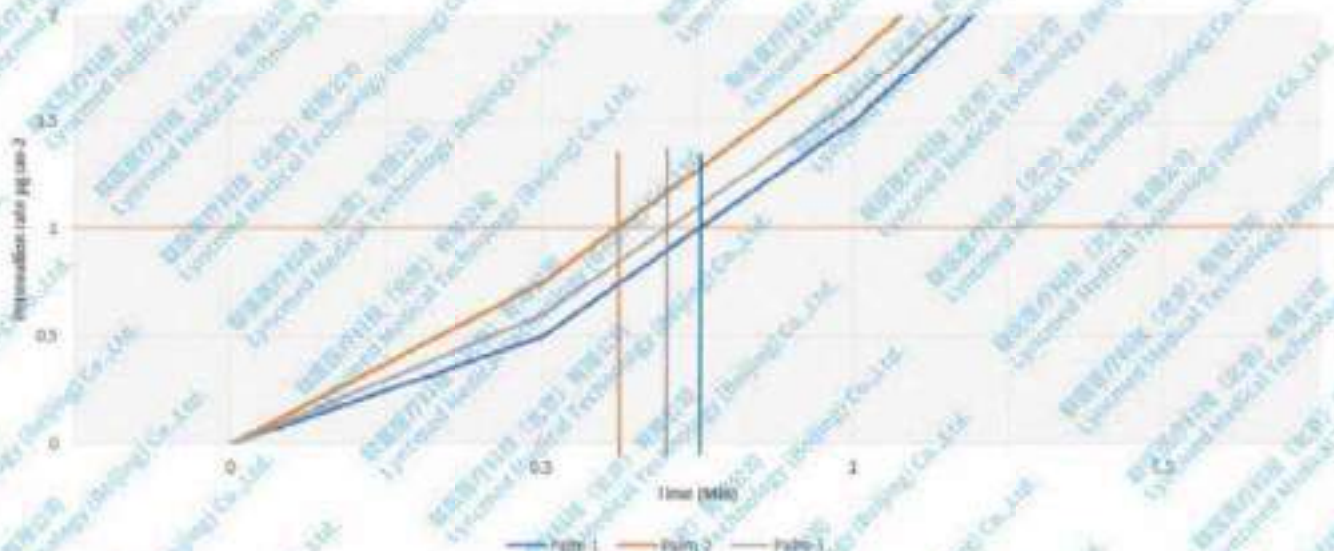
DATE : 25/01/2019



SHHL1611067691SD

RESULTS

Methanol Permeation Graph



EN 374-4:2013 Protective Gloves against Chemicals and Micro Organisms – Determination of resistance to degradation by chemicals

Chemical / CAS NO	Exposure Duration	Test Results		Observation
		Percentage change in puncture resistance		
Methanol 67-56-1	60±5 minutes	<u>Glove sample</u>	<u>Result (%)</u>	Severe swelling
		1	38.8	
		2	48.7	
		3	45.2	
		Mean	44.3	
		Standard Deviation	5.045	

***** End of Report *****

Test Report

No.: QDHL1806013408MD

Date: JUL.09.2018

Page 1 of 3

LYNCMED MEDICAL TECHNOLOGY (BEIJING) CO., LTD.
NO. 1111, SOUTH HUIHE ROAD, CHAOYANG DISTRICT, BEIJING, CHINA 100020

The following samples were submitted and identified by/on behalf of the client as:

Name of Product/Item	NITRILE EXAMINATION GLOVES
SGS Ref. No.	SL218022416072TX
Size	M
Country of Origin	CHINA
Test Performed	Selected test(s) as requested by applicant against EN 420:2003+A1:2009
Sample Receiving Date	JUN.21.2018
Testing Period	JUN.21.2018 TO JUL.09.2018
Test Result(s)	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. For further details, please refer to the following page(s).

Summary of test results:

Chemical tests

Test Item	Result
pH Value	Pass

EN 420:2003+A1:2009

Test item	Result	Level of performance
5.1 & 6.1 Sizing	8	-
5.2 & 6.2 Dexterity (mm)	5	5

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Approved by:



Zhou Xinkuan, SK
Lab Manager



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Test Report

No.: QDHL1806013408MD

Date: JUL 09, 2018

Page 2 of 3

Test Result

pH Value
EN 1413:1998

Test Item
pH value
Conclusion

7.5
Pass

Note:

- Requirement of EN 420:2003+A1:2009: greater than 3.5 and less than 9.5

Clause 5.2 Dexterity

Specimen	Smallest diameter of pin fulfilling test conditions (mm)	Level of performance (#)
1	5	5
2	5	
3	5	
4	5	

Remark: # = The performance level is defined as the smallest diameter of pin that can be picked up.

Level of performance	Smallest diameter of pin fulfilling test condition (mm)
1	11
2	9.5
3	8
4	6.5
5	5

Clause 5.1.2 & 6.1 Sizing

Claimed size	Length of glove (mm)	Glove size
M	242	8

Note: Sizes of hands (reference only)

Hand size	Hand circumference (20 mm from the crotch between thumb and index finger)	Hand length (mm)
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204
11	279	215

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NO. 1111, SOUTH HUIHE ROAD, CHAOYANG DISTRICT, BEIJING, CHINA 100020

The following samples were submitted and identified by/on behalf of the client as:

Name of Product/Item : NITRILE EXAMINATION GLOVES
Country of Origin : CHINA
Sample Receiving Date : JUN.21,2018
Testing Period : JUN.21,2018 TO JUL.09,2018
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE -
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.
Approved by:



Zhou Xinkuan, SK
Lab Manager

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Test Conducted:

EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample	: 200 Pieces
The type of gloves	: examination/procedure gloves
Manufacturing batch code	: /
Batch size	: /
Sample size	: M
Number of non-conforming gloves	: 0
Defects observed before testing	: No defects
Test Result	: Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	—	—
5.1	Referee testing	Pass	#1

Notes : #1 See result 1

Test Result:

1. Watertightness test for detection of holes

Sample Quantity: 200

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

Remark: The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.



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Sample Photo:

Received sample



SGS authenticate the photo on original report only

End of Report

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Test Report

No.: QDHL1810022710MD

Date: OCT.30,2018

Page: 1 of 5

LYNCMED MEDICAL TECHNICAL(BEIJING)CO., LTD

ROOM 119, NO.1111, SOUTH HUIHE ROAD, CHAOYANG DISTRICT, BEIJING

The following sample(s) was/were submitted and identified by the client as:

Sample Description : NITRILE GLOVE

SGS Ref. No. : SHHL1810057370MD

Sample Receiving Date : OCT.16,2018

Testing Period : OCT.16,2018 TO OCT.30,2018

Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT

Test Requested : EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE –
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL
PROPERTIES

Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)

Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd.

Approved by:



Zhou Xinkuan, SK
Lab Manager



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Test Report

No.: QDHL1810022710MD

Date: OCT.30.2018

Page: 2 of 5

Test Conducted:

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

Number of test sample	39 Pieces
The type of gloves	examination/procedure gloves b)
Manufacturing batch code	/
Size	Surgical gloves: / Examination/procedure gloves: M
Defects observed before testing	No defects

Clause	Test Items	Result	Note
4	Dimensions	---	---
4.2	Length	Pass	# 1
4.3	Width	Pass	# 1
5	Strength	---	---
5.2	Force at break	Pass	# 2
5.3	Force at break after challenge testing	Pass	# 2

Notes : #1 See result 1
#2 See result 2



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Test Report

No.: QDHL1810022710MD

Date: OCT.30,2018

Page: 3 of 5

Test Result:

1. Dimensions

Sample Quantity: 13pcs

Size	M												
Length(mm)	242	243	234	244	245	240	239	243	243	243	240	248	238
Width(mm)	96	95	96	95	95	95	95	96	98	95	95	96	96

Median value:

Length (mm): 243

Width (mm): 95

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥ 250	67 ± 4
5.5	≥ 250	72 ± 4
6	≥ 260	77 ± 5
6.5	≥ 260	83 ± 5
7	≥ 270	89 ± 5
7.5	≥ 270	95 ± 5
8	≥ 270	102 ± 6
8.5	≥ 280	108 ± 8
9	≥ 280	114 ± 6
9.5	≥ 280	121 ± 6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≥ 110



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Test Report

No.: QDHL1810022710MD

Date: OCT.30,2018

Page: 4 of 5

2. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	5.0	5.0	5.6	5.6	5.8	5.2	6.5	6.2	5.2	6.1	5.6	6.4	6.9
Force at break after challenge testing(N)	7.8	8.2	6.0	8.3	9.7	6.9	8.6	6.3	8.5	8.0	8.5	7.3	8.3

Median value:

Force at break during shelf life (N): 6.2

Force at break after challenge testing (N): 8.2

Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9.0	≥ 6.0	≥ 3.6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene). c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			



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Sample Photo:

Received sample



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Test Report

No.: SHHL1811067691SD-01

Date: APR. 02, 2019

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LYNCMED MEDICAL TECHNOLOGY (BEIJING) CO., LTD

ROOM 119, FLOOR 1, GUOTOUSHANGKE BUILDING NO. 1111, SOUTH HUIHE ROAD
CHAOYANG DISTRICT, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1811067691SD,
DATE: MAR. 29, 2019, ORIGINAL REPORT SHALL BE INVALID.
THE TEST REPORT UPDATED PROTOCOL

Sample Description	NITRILE GLOVE
Style No.	: M
Sample Receiving Date	: NOV. 27, 2018
Testing Period	: NOV. 27, 2018 TO APR. 02, 2019
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Result(s)	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Melody



Melody Zhang
Authorized Signatory



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Test Conducted:

BS EN 455-3:2015 Medical glove for single use-part 3: Requirements and testing for biological evaluation		
Clause	Test Category	TEST RESULT
4.1	General – sensitization (Maximization method)	PASS (SEE RESULT PAGE)
4.3	Endotoxins	PASS (SEE RESULT PAGE)
4.4	Powder	PASS (SEE RESULT PAGE)
4.5	Protein, Total leachable	NA
4.6	Labelling	NC

REMARK: NA = Not Applicable NC = Not conducted as per client's request



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Test Result Page:

Attachment 1: Test for Irritation (Animal skin Irritation test)

SUMMARY

The animal skin irritation test of the test article, Nitrile Glove, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10: 2010: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and skin sensitization, ISO 10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article:	Nitrile Glove
Sterilization Status:	Non-sterile
Storage Conditions:	Room temperature
Extraction Vehicle:	0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
Test Article Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO 10993-12:2012, the ratio of 8cm ² :1 ml (Surface area of the test sample to volume of extraction



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Reaction	Primary Irritation Score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test article and the negative control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites x 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test article were obtained. A similar calculation was made with the negative control. The primary irritation index was obtained by subtracting the score of the negative control from the test article score and the response categories were given as below:

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe



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RESULTS

All animals appeared clinically normal throughout the study. All sites of the test extract and the reagent control appeared normal following removal the patches; the score of the test extract and the reagent control all were 0.

The Primary Imitation Index (PII) of the test article was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test article to rabbits. The response category for the extracts of the test article was negligible.

[illegible]

4. Hattley, R. 1993. *Wetland Forest*. Johns Hopkins University Press.

1. 1993-1994

† 800-275-5000

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PHOTOGRAPH OF THE TEST ARTICLE

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The following test was performed by SGS other internal laboratory

BS EN 455-3:2015 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample	: 5 Pieces
Finishes of gloves	: Powdered-free gloves, other than surgeon's gloves
Defects observed before testing	: No defects
Test Result	: Pass

Clause	Test Items	Result	Note
4.4	Powder-free gloves	Pass	# 1

Notes : #1 Test according to EN ISO 21171:2006, the average mass of powder per glove was 0.06mg.

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