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MEDICAL EXAMINATION GLOVE

NITRILE GLOVES · LATEX GLOVES · VINYL GLOVES

LyncMed

LyncMed Group Corporation

Room 1601, Building No.2, Zhubang 2000 Business Building, Balizhuangxili 99, Chaoyang District, 100022 Beijing,China.

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NITRILE GLOVES


NITRILE
EXAMINATION GLOVES
S

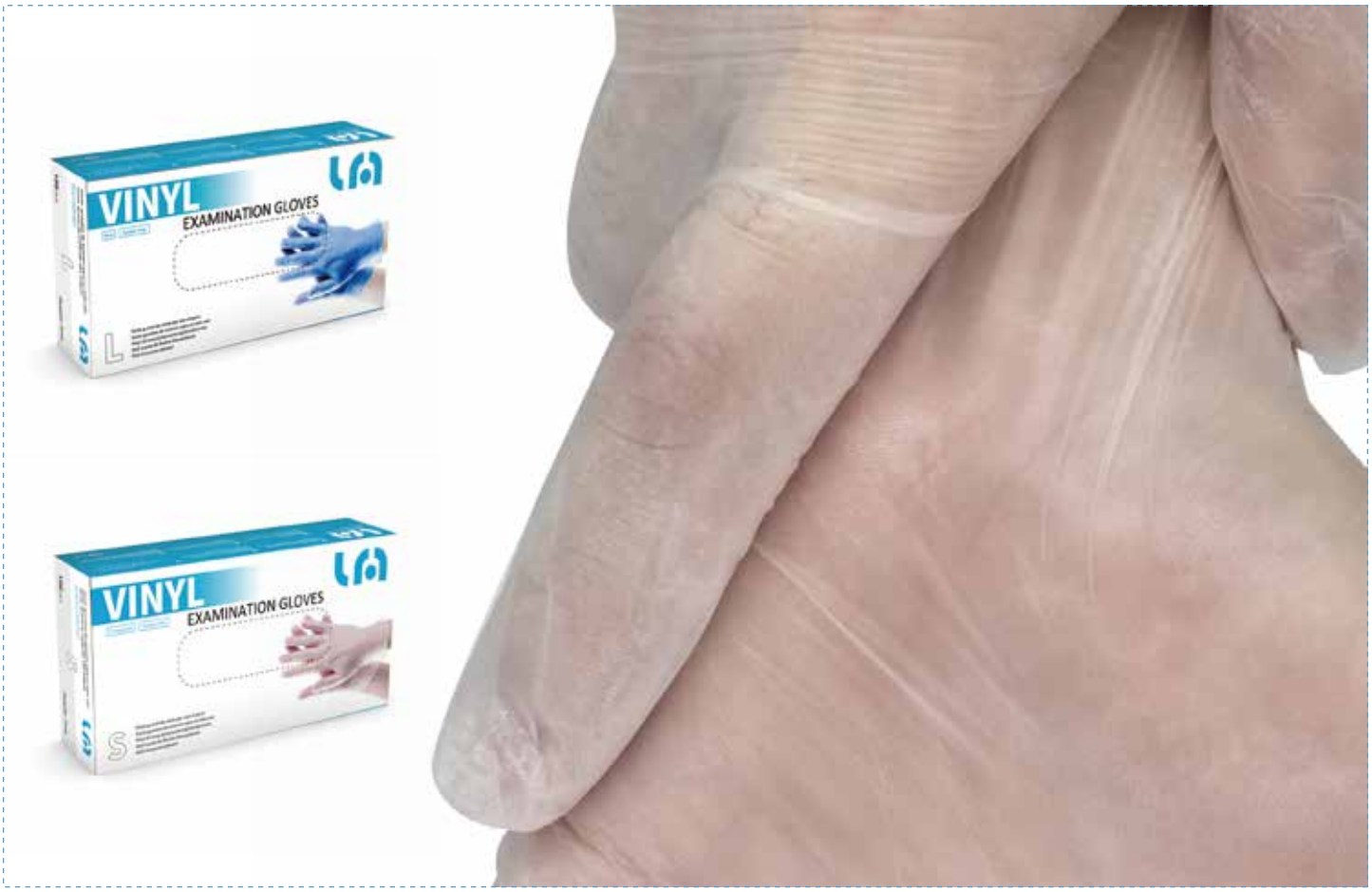

NITRILE GLOVES
XL

LATEX GLOVES


LATEX
EXAMINATION GLOVES
NATURAL LATEX EXAMINATION GLOVES
Powder Free
L
Large
P.F
NATURAL

VINYL GLOVES

Clear/Blue/Black



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-Comfortable style, according to ergonomic design glove palm machine bending fingers to wear comfortable, conducive to blood circulation. Does not contain protein, amino compounds and other harmful substances, rarely produce allergies.
-Widely used in electronics factories, medical inspection, food industry, domestic labor, chemicals, aquaculture, glass products and scientific research and other industries.

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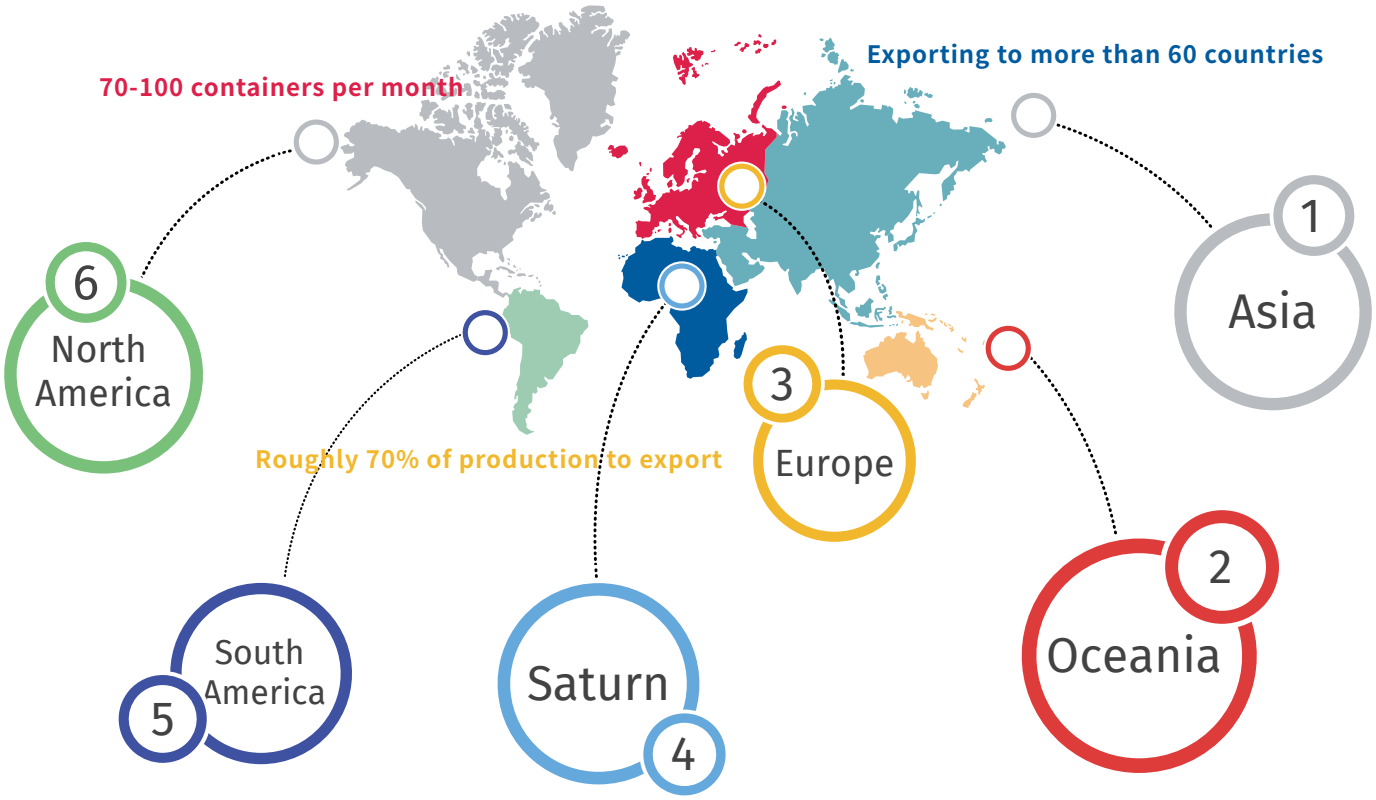

LyncMed has sales offices across the world including Italy, Spain, Germany, Mexico, American, Portugal and Turkey with additional warehouses in strategically placed locations to support distributions on a global scale.

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Risk Control & Management

SGS Inspection and Quality Control

Our factory

production line

MODEL: Sample -Nitrile gloves

PRODUCT INFORMATION	
Material	100% Nitrile
Color	Blue, Violet
Cuff length	Standard
Glove length(mm/inches) min	240mm\9.4inch
Powder content	≤2 mg per glove
External glove surface	Textured Finger
Freedom from holesflnspection level 1)	1.5 AQL
Tensile strength	≥ 6.0 N
Application Temperature	<40°C

Specification	Size	Length(mm)	Width(mm)
LM-NG-01	S	>240	≦80
LM-NG-02	M	>240	95±10
LM-NG-03	L	>240	110±10
LM-NG-04	XL	>240	≧110

Medical examination nitrile gloves

Medical examination nitrile gloves are intended to be worn on the hands of healthcare personnel to prevent contamination between patients and examiners.This is a single-use,powderfree,non-sterile device.

FEATURES

1. Excellent mechanical strength provides a high level of hand protection.
2. Textured in finger tips for a secure grip.
3. Skin irritation&sensitization tested.

MANUFACTURING ACCREDITATIONS

ISO 13485 Medical Device Quality Management System

REGULATROY COMPLIANCE

MDR 2017/745
EN455

STORAGE INSTRUCTIONS

Package Components

Exterior Package Design

Inner box size:220×120×63 mm
100PCS
Carton size:330×230×220 mm
1000PCS

MOQ: 1*40HQ : 4000-4200 cartons

Delivery Time: 10-12 weeks upon the date of confirmed the final artwork and prepayment
Size Ratio: S+M>60%. If L+XL >60%, price will be adjusted.
Payment Term: 50% prepayment, 50% payment against copy of BL.

SGS

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

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101 t (86-532) 68999187 f (86-532) 80991952 www.sgsgroup.com.cn
中国·青岛·崂山区株洲路143号通标中心 邮编: 266101 t (86-532) 68999187 f (86-532) 80991952 e sgs.china@sgs.com

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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	7.5
Conclusion	**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

QDHL 001263

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Certificates –EN420 Test Report

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Test Report No.: QDHL1806013408MD Date: JUL.09,2018 Page 3 of 3

Sample Description : One sample of nitrile examination glove in blue

Sample Photo:

SGS authenticate the photo on original report only

*** End of Report ***

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中国・青岛・崂山区株洲路143号通标中心 邮编: 266101 t (86-532) 68999187 f (86-532) 80991952 e sgs.china@sgs.com

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Test Report

Report No.: QDHL2009009945MD

Sample Description: NITRILE EXAMINATION GLOVES

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

Test Type: SUBMITTED BY CLIENT

SGS

Test Report

Sample information	Sample Description	NITRILE EXAMINATION GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	220PCS/ 200PCS	Type/Specifications	EXAMINATION/ L
	Lot No.	LMNE 20200916	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NITRILE	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
Client information	Applicant	LYNCMED MEDICAL TECHNOLOGY (BEIJING) CO., LTD.		
	Applicant address	ROOM 1601, BUILDING NO.2,ZHUBANG 2000 BUSINESS BUILDING, BALIZHUANG XILI 99, CHAOYANG DISTRICT, 100022 BEIJING, CHINA		

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Test information	Sample Receiving Date	SEP.25,2020	Test Period Date	SEP.25,2020 TO OCT.16,2020
	Sample No.	QDHL2009009945MD	Test environment	Meet requirement
	Test items	Water tightness test		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: OCT.16,2020			
Remark	/			

Approver: Jessica Guo Auditor: Jessica Guo Compiler: Lillian Diao

Date: OCT.16,2020 Date: OCT.16,2020 Date: OCT.16,2020

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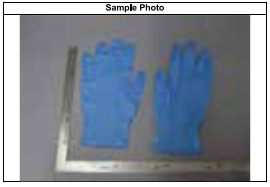
Sample Photo



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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

statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.
2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.
3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.
5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address: SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101 Fax: 0532-80991952

E-mail：Emily.Zhang@sgs.com

Certificates –EN455-2 Test Repor

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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

SGS

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

SGS

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	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±6
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	6.6	6.6	5.8	5.2	6.6	6.2	5.2	6.1	6.6	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	≥ 5.0	≥ 6.0	≥ 3.6

a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polychloroprene, polyethylene).
c) Requirements for gloves made from thermoplastic materials (e.g. polychloroprene, polyethylene).

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Test Report No.: QDHL1810022710MD Date: OCT.30,2018 Page: 5 of 5

Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

Certificates –EN455-3 Test Repor

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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 1 of 10

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 Zhang
Authorized Signatory

SGS

Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 2 of 10

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 Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 3 of 10

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 6cm²:1 ml (Surface area of the test sample to volume of extraction

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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 4 of 10

vehicle), 90cm² of the test articles were covered with 15ml of extraction vehicle under aseptic conditions for preparing the SC and CSO test extract at 37 °C for 72h respectively. The extracts were used after extraction.

Reagent Control:	The extraction vehicles (without test article) were similarly prepared to serve as the reagent control.
Condition of extracts:	All the extract of the test and controls were clear.

In addition, according ISO 10993-10 requirement, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2018.12.24~2018.12.28). Complete data is traceable in laboratory records.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Male
Body weight range:	2.4 kg ~ 2.5 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel

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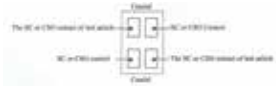
Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 5 of 10

suspended cages identified by a card indicating the Identification No of the test article and first treatment date.

Environmental:	The room temperature and humidity was monitored daily. The room temperature range was from 20°C to 26°C. The room humidity range was from 50% to 70%.
Personnel	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10 cm x15 cm. A 25 mm×25 mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to the test sites. The extract of test article and the reagent control were directly applied to the region as illustrated below:



The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24 h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours.
The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.

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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 6 of 10

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-define 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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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 7 of 10

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 Irritation 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.

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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 8 of 10

PHOTOGRAPH OF THE TEST ARTICLE

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Test Report No.: SHHL1811067691SD-01 Date: APR. 02, 2019 Page: 9 of 10

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.

Remark:
1. Since the data and / or information above division line of front page is provided by the applicant, the relevant results or conclusions of this report are only made for these data and / or information, SGS is not responsible for the authenticity, integrity and results of the data and information and / or the validity of the conclusion. Testing results only apply to the sample as received.
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Certificates –EN374 Test Report

SGS

TEST REPORT

Report No. : CH:TX:1042003821 DATE : 25/01/2019
1042003821 SHHL1811067691SD

LYNCMED MEDICAL TECHNICAL(BEIJING)CO.,LTD
ROOM 119, FLOOR 1, GUOTOUSHANGKE BUILDING NO 111, SOUTH HUIHE R
CHINA
A/C F619301 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
STYLE NO, M
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 pentration	
	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.

Per pro SGS India Private Ltd.

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

SGS

TEST REPORT

Report No. : CH:TX:1042003821 DATE : 25/01/2019
1042003821 SHHL1811067691SD

RESULTS

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

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 µg 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 requirments 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 achived per chemical

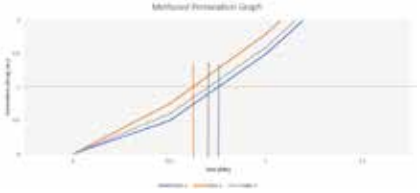
***** End of page*****

SGS

TEST REPORT

Report No. : CH:TX:1042003821 DATE : 25/01/2019
1042003821 SHHL1811067691SD

RESULTS



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 Percentage change in puncture resistance		Observation
		Glove sample	Result (%)	
Methanol 67-56-1	60±5 minutes	1	38.8	Severe swelling
		2	48.7	
		3	45.2	
		Mean	44.3	
		Standard Deviation	5.045	

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

Certificates –EN1186 Test Report

SGS

Test Report No. SHAHG1826661102 A01 Date: 07 Dec 2018 Page 1 of 4

LYNCMED 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. : SHHL1811067540CW - 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
Approved Signatory

SGS

Test Report No. SHAHG1826661102 A01 Date: 07 Dec 2018 Page 2 of 4

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/dm²	<3.0mg/dm²	PASS
20% Ethanol (V/V) Aqueous Solution	2.0hr(s)	40°C	10mg/dm²	<3.0mg/dm²	PASS
50% Ethanol (V/V) aqueous solution	2.0hr(s)	40°C	10mg/dm²	<3.0mg/dm²	PASS
95% Ethanol	2.0hr(s)	40°C	10mg/dm²	8.2mg/dm²	PASS
Isooctane	0.5hr(s)	40°C	10mg/dm²	<3.0mg/dm²	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

SGS

Test Report No. SHAHG1826661102 A01 Date: 07 Dec 2018 Page 3 of 4

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

Test Item(s)	Limit	001
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	001
Volatile organic matter (VOM)	0.50	% (w/w)	0.10	0.12
Conclusion				PASS

SGS

Test Report No. SHAHG1826661102 A01 Date: 07 Dec 2018 Page 4 of 4

Sample photo:

SGS authenticate the photo on original report only

*** End of Report ***

Lyncmed Company Certificate

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q6 099730 0004 Rev. 02

Holder of Certificate: **Lyncmed Medical Technology (Beijing) Co., Ltd.**
Room 1601, Building No. 2
Zhubang 2000 Business Building, Balizhuang Xili 99
Chaoyang District
100022 Beijing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD tuv-sud.com/ps-cert

Scope of Certificate: **Distribution, Production and Sales of Dental high speed air turbine handpieces, Dental low speed air turbine handpieces, Ultrasonic Scaler, LED Curing Lights, Root Apex locators, Endo motors, Pulp tester, Portable Dental Unit, Dental Implant Systems, Dental Alginate Mixers, Sterile Surgical Gowns, Sterile Surgical Packs, Sterile Surgical Drapes, Sterile Dressing Pouches, Caps, Face mask, Shoe cover, Bed cover, Protective coverall, Urine bag, Foley Catheter, Oxygen Mask, Nebulizer Mask, Laryngeal Mask, Anaesthetic Mask, Wheelchair, Walker, Crutch.**

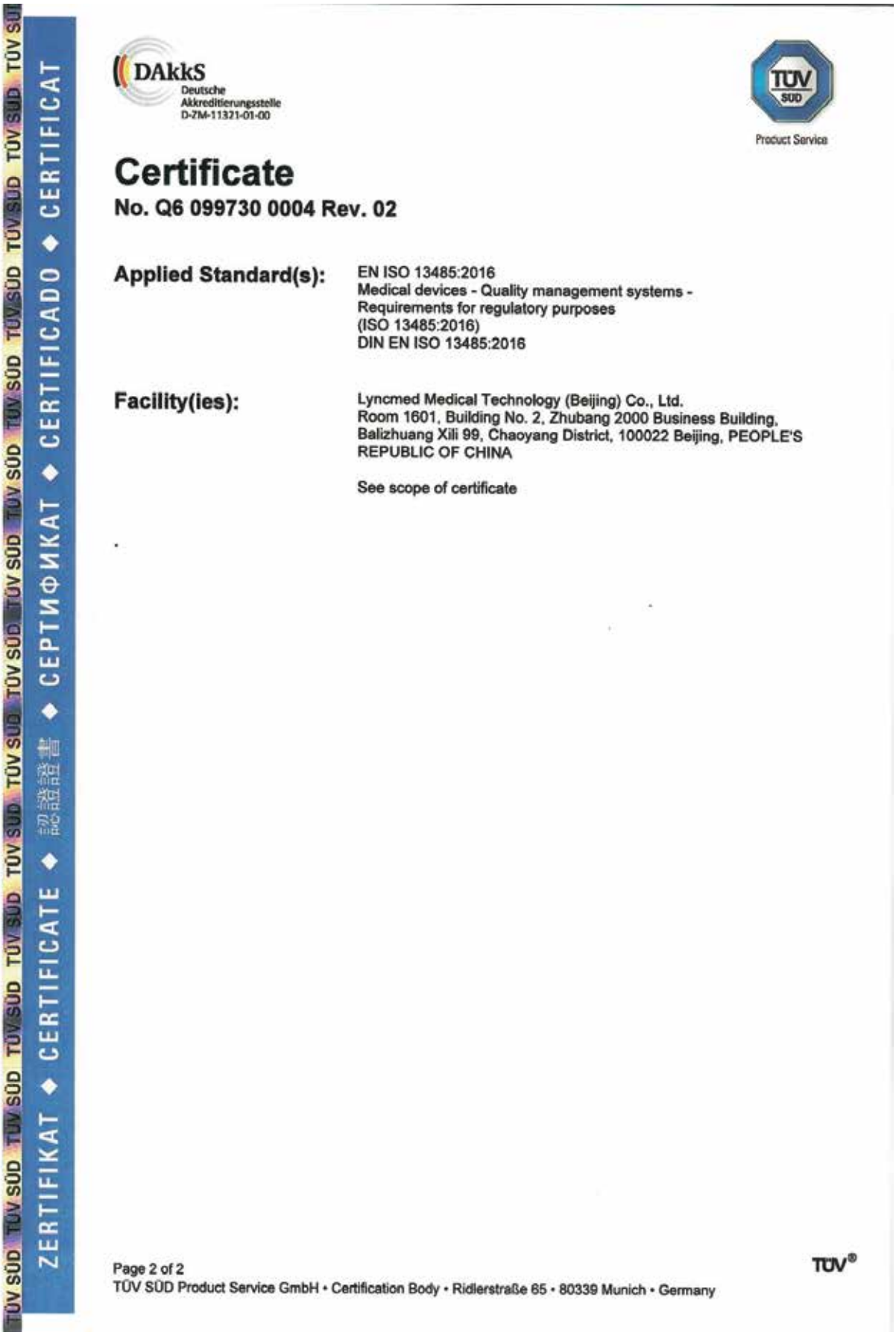
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 099730 0004 Rev. 02

Report No.: BJ20020501
Valid from: 2020-12-20
Valid until: 2023-12-19

Date, 2020-12-11

Christoph Dicks
Head of Certification/Notified Body

Lyncmed Company Certificate



DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 099730 0004 Rev. 02

Applied Standard(s):

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

Facility(ies):

Lyncmed Medical Technology (Beijing) Co., Ltd.
Room 1601, Building No. 2, Zhubang 2000 Business Building,
Balizhuang Xili 99, Chaoyang District, 100022 Beijing, PEOPLE'S
REPUBLIC OF CHINA

See scope of certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Page 2 of 2
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TÜV®

Lyncmed Company Certificate

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148110 0001
Report No.: 50180180 006

Organization:
Lyncmed Medical Technology
(Beijing) Co., Ltd.
Room 1601, Building No.2
Zhubang 2000 Business Building, Balizhuangxili
Chaoyang District
100022 Beijing
P.R. China

Scope:

Products:

Sterile Latex Surgical Gloves, Non-sterile Examination Latex Gloves, Dental High Speed Air Turbine Hand-pieces, Dental Low Speed Air Turbine Hand-pieces, Patient Examination Gloves, Ultrasonic Scaler, Endo Motors, Apex Locators, Pulp Testers, Masks, Laryngeal Mask Airways, Overalls, Isolation Gowns, Sterile Surgical Gowns, Sterile Surgical Kits, Sterile Surgical Caps, Sterile Face Masks, Sterile Shoe Covers, Alcohol Swabs, Diapers and Adult Diapers, Disposable Under Pads, Medical Tapes, Urine Bags for Single Use, Foley Catheter Silicone, Dental Alginate Mixers, Vinyl Examination Gloves and Sterile Gauze Sponges

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

Certification Body

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Date: 2020-06-22

Jing Zhang

Lyncmed Company Certificate

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Lyncmed Medical Technology (Beijing) Co., Ltd.
Room 1601, Building No.2
Zhubang 2000 Business Building, Balizhuangxili 99
Chaoyang District
100022 Beijing
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(See attachment for Products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-06-22
Certificate Registration No.:	SX 60148110 0001
An audit was performed Report No.:	50180180 006
This Certificate is valid until:	2021-12-03

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

Date 2020-06-22

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

Government Approved Qualified Manufacturer Name List

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

http://www.cccmhpie.org.cn/

序	生产企业	统一社会信用代码	国外注册认证情况
No.	Company	Uniform Social Credit Code	Status of Certification / Authorization in Other Countires
一、 医用口罩 Medical Face Masks			
1	稳健医疗用品股份有限公司 Winner Medical Co., Ltd.	91440300723009295R	CE
2	湖北省潜江市江赫医用材料有限公司 Hubei Qianjiang Kingphar Medical Material Co.,Ltd	914290051836675600	CE
3	合肥美地普医疗卫生用品有限公司 Hefei Medpro Healthcare Co., Ltd.	91340100744891942W	CE
4	海安美佳医用敷料有限公司 Haian Medigauze Co.,Ltd.	91320621733774564Q	CE
5	湖北康宁防护用品有限公司 Hubei Kangning Protective Products Co.,Ltd.	914290047959276261	CE
6	仙桃市兴荣防护用品有限公司 Xiantao Xingrong Protective Products Co., Ltd.	91429004753447771A	CE
7	奥美医疗用品股份有限公司 Allmed Medical Products Co.,Ltd.	9142058373914001XH	CE
8	金士达医疗(咸宁)有限公司 Kingstar Medical (Xianning) Co.,Ltd.	91421200080935876P	CE
9	江苏省健尔康医用敷料有限公司 Jiangsu Province Jianerkang Meddical Dressing Co., Ltd	91320413714946201R	CE
10	安徽天康医疗科技股份有限公司 Anhui Tiankang Medical Technology Co.,Ltd	9134110071990801XY	CE
11	苏州恒祥进出口有限公司 Suzhou Hengxiang Import &Export Co.,Ltd.	91320508724448775B	CE
12	河南康灸来医疗科技有限公司 Henan Kanjoray Medical Technology Co., Ltd.	91410600MA46CYC12X	CE
13	联医医疗科技（北京）有限公司 LyncMed Medical Technology (Beijing) Co., Ltd.	91110108MA002T3N4R	CE
14	威海威高医疗国际贸易有限公司 Weihai Medical International Co., Ltd.	9137100005624731X3	CE

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