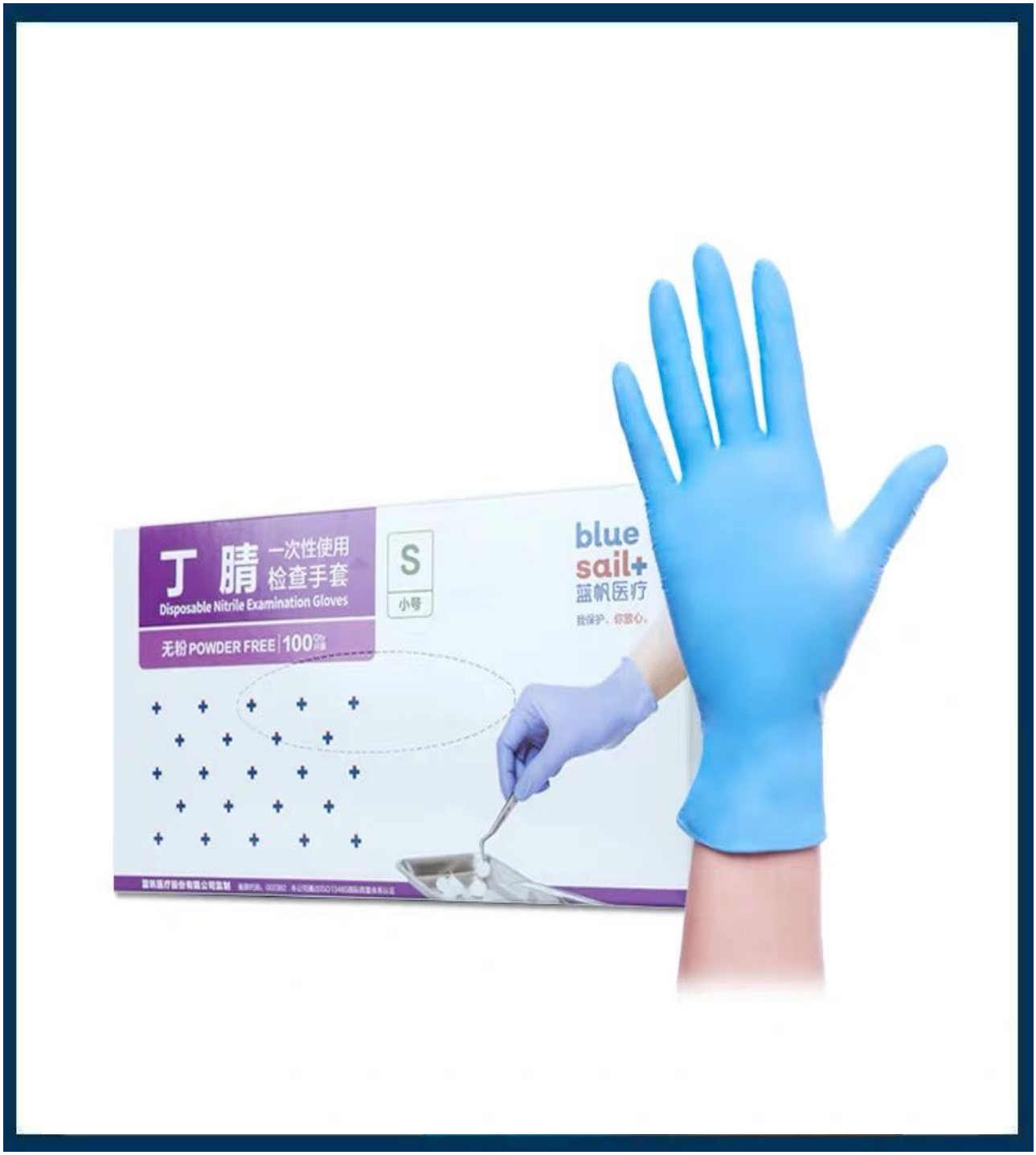
蓝帆医疗丁腈手套技术文件清单

生产厂家简介

蓝帆医疗股份有限公司简称“蓝帆医疗”（股票代码 002382），成立于 2002 年，为中港合资企业，是蓝帆集团的下属医疗产业板块。

公司于 2010 年 4 月 2 日成功在深交所上市，是国内健康防护手套行业第一家上市公司，主要产品为一次性 PVC 手套、一次性丁腈手套和一次性 PE 手套，产品全部出口，遍布 100 多个国家和地区，广泛应用于医疗卫生、日常清洁、精密器件加工、家庭保洁、化学试验以及食品加工等领域。

蓝帆医疗是中国一次性使用医用检查手套标准起草单位，为“山东省 PVC 手套工程技术研究中心”，“蓝帆”品牌于 2014 年 9 月获得“中国驰名商标”称号。


丁腈 一次性使用
检查手套
Disposable Nitrile Examination Gloves
S
小号
无粉 POWDER FREE | 100
blue
sail+
蓝帆医疗
我保护，你放心。

品牌：	品名：
蓝帆医疗	一次性丁腈手套
材质：	尺寸：
丁腈化合物	XS/S/M/L/XL
类型：	长度：
无粉	9 寸
颜色：	
白色、蓝色、黑色、钴蓝色、蓝紫色	

营业执照

（副 本） 1-1

统一社会信用代码

91370000744521618L

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息

名　　称　蓝帆医疗股份有限公司

类　　型　股份有限公司(台港澳与境内合资、上市)(外资比例低于25%)

法定代表人　刘文静

经营范围　生产加工PVC手套、丁腈手套、一类、二类、三类医疗器械、其他塑料制品、粒料，销售本公司生产的产品；丁腈手套、乳胶手套、纸浆模塑制品、一类、二类医疗器械产品的批发业务。(依法须经批准的项目，经相关部门批准后方可开展经营活动，有效期以许可证为准。)

注册资本　人民币 玖亿陆仟肆佰零叁万壹仟零捌拾陆元整

成立日期　2002 年 12 月 02 日

营业期限　2002 年 12 月 02 日 至　　年　　月　　日

住　　所　山东省淄博市齐鲁化学工业区清田路21号

登记机关　山东省市场监督管理局

2019 年 10 月 24 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告

国家市场监督管理总局监制

第一类医疗器械备案凭证

蓝帆医疗股份有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用检查手套予以备案，备案号：鲁淄械备20180093号

淄博市食品药品监督管理局

（盖章）

日期：2018年10月09日

第一类医疗器械备案信息表

备案号：鲁淄械备 20180093 号

备案人名称	蓝帆医疗股份有限公司
备案人组织机构代码	91370000744521618L（境内医疗器械适用）
备案人注册地址	山东省淄博市齐鲁化学工业区清田路 21 号
生产地址	山东省淄博市齐鲁化学工业区清田路 21 号
代理人	（进口医疗器械适用）
代理人注册地址	（进口医疗器械适用）
产品名称	医用检查手套
型号/规格	XS、S、M、L、XL
产品描述	通常采用聚氯乙烯、橡胶等材料制造。有足够的强度和阻隔性能。 非无菌提供，一次性使用。
预期用途	用于戴在医生手上或手指上对患者病情进行检查或触检。
备注	
备案单位和日期	淄博市食品药品监督管理局 备案日期：2018 年 10 月 09 日
变更情况	

产品说明书

【产品名称】医用检查手套

【规格型号】 XS、S、M、L、XL。

表 1　尺寸和公差　　单位：mm

规格	标称宽度 （图 1 中w）	最小长度 （图 1 中l）	最小厚度 （图 2 中所示位置）	最大厚度 （大约在手掌的中心）
XS	≤80	220	光面区域：0.08 麻面区域：0.11	光面区域：2.00 麻面区域：2.03
S	80±5	220		
M	95±5	230		
L	110±5	230		
XL	≥110	230		

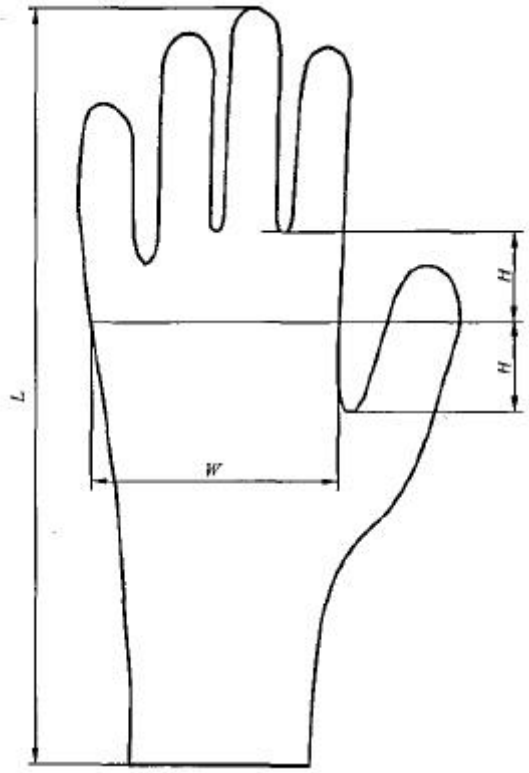
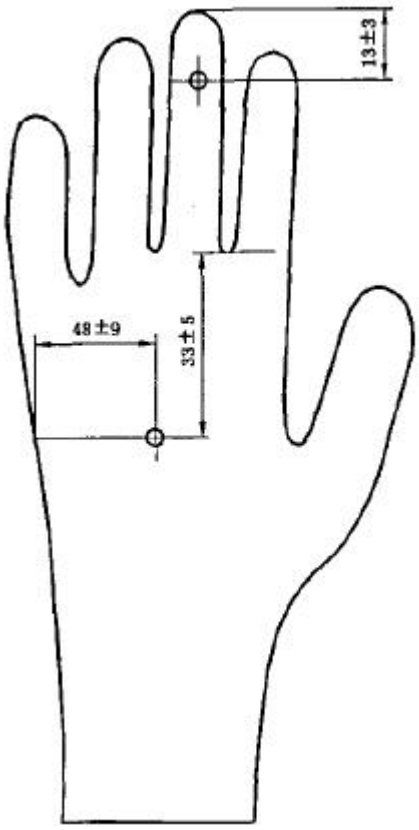


图 1 宽度和长度测量位置



注：对于不同规格的手套，48mm±9mm 位置在大约手掌的中心位置。

图 2 厚度的测量位置

【产品性能】

1. 老化前扯断力≥7.0N；
2. 老化前扯断伸长率≥500%；
3. 老化后扯断力≥7.0N；
4. 老化后扯断伸长率≥400%；
5. 有粉手套表面残余粉末含量不大于 10mg/dm^2。无粉手套表面残余粉末含量不大于 2.0mg/只。

【主要结构组成】

医用检查手套主要采用丁腈橡胶胶乳材料制造。按表面型式分为麻面、光面、有粉、

无粉四种，有粉表面采用玉米淀粉进行表面处理。

【适用范围】

用于戴在医生手上或手指上对患者病情进行检查或触检。

【禁忌症】

对丁腈橡胶胶乳过敏者禁用。

【注意事项】

1.本品为一次性使用，用后注意销毁。

2.对使用丁腈手套有不良反应者慎用。

3.包装破损，禁止使用。

4.本产品为非无菌。

【使用说明】

1.选取适合自己手型大小的手套，打开包装，取一只手套以左手拇指、食指及中指提住撑开手套口，迅速将右手伸入手套内，使各指尖直达手套顶部之顶端。不露出手腕。

2.将左手同上法插入手套中。

3.脱手套时，应将手套反转轻轻脱下，手尽量不要碰到手套外面。

【贮存条件】

应贮存在相对湿度不得超过 80%，无腐蚀性气体和通风良好的室内。

【运输条件】 运输过程中要防晒，防雨淋。

【生产日期】见产品标签。

【失效日期】见产品标签。

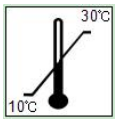
【使用期限】三年。

【医疗器械标签所用图形、符号、缩写等内容的解释】

：本产品用于一次性使用

：本产品要避光储存

：本产品要防雨储存



：本产品适宜储存温度为 10℃到 30℃

【备案人/生产企业名称】蓝帆医疗股份有限公司

【备案人/生产企业住所】山东省淄博市齐鲁化学工业区清田路21号

【生产地址】山东省淄博市齐鲁化学工业区清田路 21 号

【联系方式】电话：0533-785 5150

【售后服务单位】蓝帆（上海）贸易有限公司

杭州蓝帆健康科技有限公司

【联系方式】电话：021-38682775　　0533-7871098

【生产备案凭证编号】鲁淄食药监械生产备 20140003 号

【产品备案凭证编号】鲁淄械备 20180093 号

【产品技术要求的编号】鲁淄械备 20180093 号

【说明书编制/修订日期】2018 年 9 月 26 日

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

Product Service

Certificate

No. Q5 062837 0012 Rev. 02

Holder of Certificate: **Blue Sail Medical Co., Ltd**
No.21, Qingtian Road, Qilu Chemical Industrial Area
255414 Zibo, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of Disposable Vinyl Examination Gloves, Disposable Nitrile Examination Gloves.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ19924043

Valid from: 2019-11-12
Valid until: 2022-07-31

Date, 2019-11-12

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

Intertek Certification Ltd (UKAS 014) certifies that, having conducted an audit for the scope of activities: **Compounding, dipping, vulcanization (disposable nitrile gloves), chlorination (disposable nitrile gloves), plasticization, stripping and packaging of disposable PVC/nitrile gloves (medical examination, food contact and general use) packed in carton box or PE bag; Compounding, curtain coating, heat seal and molding and packaging of disposable PE gloves (food contact and general use) packed in carton box or PE bag,**

Exclusions from Scope: None

Product Categories: 09 - Rubber & plastic products

20 - Medical devices, at

Blue Sail Medical Co., Ltd.

BRC Site Code: 1271176

Site Address: No. 21, Qingtian Road, Qilu Chemical Industrial Park, Zibo City, Shandong Province, China 255414

Has achieved Grade: AA

Meets the requirements set out in the

BRC GLOBAL STANDARD for CONSUMER PRODUCTS

Personal Care & Household
Issue 4: November 2016

Higher Level

BRCGS Certification Body CERTIFICATED

Auditor Number:
168213

Certificate Number:
73834

Dates of Audit:
13-15 Jan 2020

Certificate Issue Date:
10 Feb 2020

Re-audit Due Date:
From 19 Dec 2020
To 16 Jan 2021

Certificate Expiry Date:
27 Feb 2021

BRC CERTIFICATION ™ Intertek

UKAS PRODUCT CERTIFICATION 014

Calin Moldovean
President Business Assurance

Intertek Certification Ltd – 10a Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of Accreditation No. 014

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Blue Sail Medical Co., Ltd
No. 21 Qingtian Rd.
Qilu Chemical Industrial Area
Zibo
Shandong
255414
China

DUNS Number: 54-404-9487

Holds certificate No: **MDSAP 696204**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 – Production Quality Assurance Procedure [if design controls are excluded from the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design, Development, Production and Distribution of Disposable Vinyl Examination Gloves, Disposable Nitrile Examination Gloves.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-01-14 Effective Date: 2019-01-14 Expiry date: 2022-01-13

...making excellence a habit.™

BSI Group America Inc. is an MDSAP authorized auditing organization

151000100270

TESTING
CNAS L2954

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-M201601762-1

Skin Sensitization Test of Powder Free Nitrile Examination Gloves Using ISO 10993-10:2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract

Sponsor

Blue Sail Medical Co., Ltd.

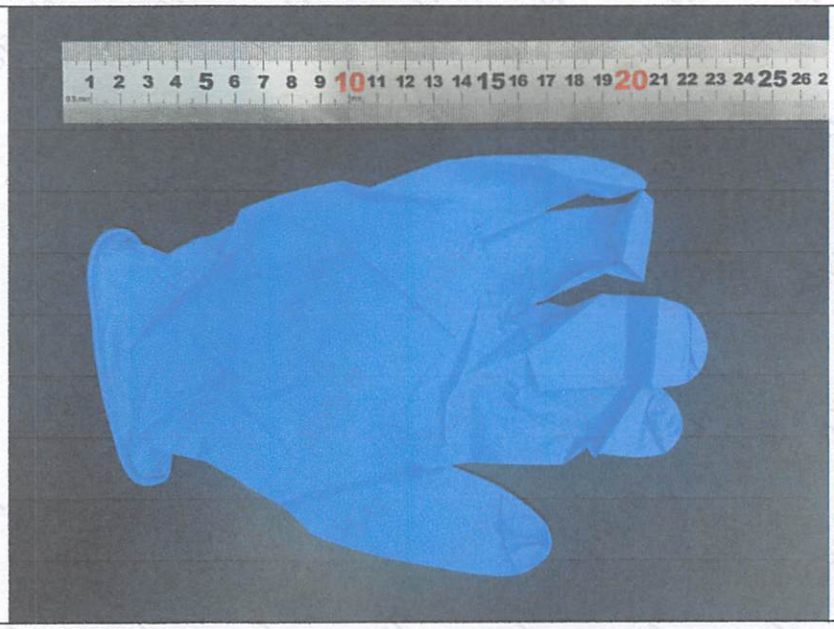
Sanitation & Environment Technology Institute, Soochow University
Tel: 0512-65880039 Fax: 0512-65880034 Email: sudaweihuan@mail.suda.edu.cn PC: 215123
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China http://yxbfzb.suda.edu.cn

CONTENTS

SUPPLEMENTARY EXPLANATION

1. Please apply for rechecking within 15 days of receiving the report if there are any objections.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.

STUDY VERIFICATION AND SIGNATURE

Test Article	
Test Article Receipt:	2016-08-03
Protocol No:	SDWH-PROTOCOL-GLP-M201601762-1
Protocol Effective Date:	2016-08-18
Technical Initiation Date:	2016-08-19
Technical Completion Date:	2016-09-15
Final Report Completion Date:	2016-09-21

Edited by : _____ 2016-09-21
Date

Checked by : _____
Study Director
2016-09-4
Date

Approved by : _____
Authorized signatory
2016-09-23
Date

Sanitation & Environment Technology Institute, Soochow University

QUALITY ASSURANCE STATEMENT

This study was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of SDWH, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to SDWH's Management.

INSPECTIONS	DATE OF INSPECTION	DATE REPORTED STUDY DIRECTOR	DATE REPORTED MANAGEMENT
EXPERIMENTAL PROCEDURE	2016-08-30	2016-08-30	2016-08-30
RAW DATA	2016-09-21	2016-09-21	2016-09-21
FINAL REPORT	2016-09-21	2016-09-21	2016-09-21

Quality Assurance Unit : Zhou Ying _____ 2016-09-21

QA Date

1.0 Study Summary

The extract of the test article Powder Free Nitrile Examination Gloves (extraction in 0.9% Sodium Chloride for Injection) was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.
The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone. The topical challenge with the test article extract elicited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.
As defined by the scoring system of Magnusson and Kligman the test article extract showed no signification evidence of causing skin sensitization in the guinea pig under the conditions of this study.

2.0Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

3.0Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58
ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No. CNAS L2954
Accreditation Criteria for the competence of the laboratories (Quality and Technical Bureau of Jiangsu Province Metrology Accreditation Certificate CMA 151000100270)

5.0Identification of test and control articles

5.1 Test article

Test article name: Powder Free Nitrile Examination Gloves

Test article initial state: Not Sterilized
CAS Code: Not supplied by sponsor (N/S)
Model: LAGER
Size: powder free blue
Lot/ Batch: N/S
Test Article Material: Nitrile
Packaging Material: N/S
Physical State: Solid
Color: blue
Density: N/S
Stability: good
Solubility: N/S
Storage Condition: Room Temperature
The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

5.2 Control article

5.2.1Negative Control

Article Name: 0.9% Sodium Chloride Injection (SC)
Manufacturer: Cisen Pharmaceutical Co., Ltd.
Size: 500ml
Lot/ Batch#: 1512290723
Physical State: Liquid
Color: Colorless
Storage Condition: Room Temperature

5.2.2Positive Control

Article Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Xiya Reagent^{R}
Size: 100g
Lot/ Batch#: W5656
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: 0.9% Sodium Chloride Injection
Date prepared: 2016-08-01
Physical State: Liquid
Color: light yellow
Storage Condition: Room Temperature

6.0Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)
Number: 15 (10 Test +5 Negative Control)
Sex: males

Initial body weight: 300 500g
Health status: Healthy, not previously used in other experimental procedures
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date, etc
Animal identification: Stain with picric acid
Cages: Plastic cage
Acclimation Period: 7 days under the same conditions as for the actual test

7.0Animal Care and Maintenance

Animal purchase: Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: Corncob, Suzhou shuangshi laboratory animal feed science Co.,Ltd
Feed: Guinea Pig Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26□
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained
Selection: Only healthy, previously unused animals were selected
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

8.0Justification of the test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at SDWH.

9.0Route of administration

The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

10.0Experiment design

10.1 Sample and Control Preparation

Intradermal induction phase Ⅰ:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

Topical induction phase II :

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

Challenge phase:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

There is no change in the extraction solvent (pre- and post-extraction). The extract was stored at 4℃ and tested within 24h after extraction without the process of pH value adjustment, filtering, centrifugation, dilution, etc.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Horizontal Large Capacity Constant Temperature Vibrator (SDWH897), Calibration Expire (2017-07-25)

Cylindrical pressure steam sterilizer (SDWH030), Calibration Expire (2017-05-24)

Steel Straight Scale (SDWH463) ,Calibration Expire（2016-09-23）

Electronic scale (SDWH442) ,Calibration Expire（2016-09-20）

10.3 Reagents

Freund's Adjuvant,Complete liquid

Manufacturer: SIGMA

Lot No: SLBL3699V

Sodium dodecyl sulfate (SDS)

Manufacturer: Sinopharm Chemical Reagent Co.Ltd

Lot No: 20150113

Concentration: 10%

Solvent: Distilled water

Date prepared: 2016-06-06

10.4 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); the control animals were injected with an emulsion of the blank liquid with adjuvant.

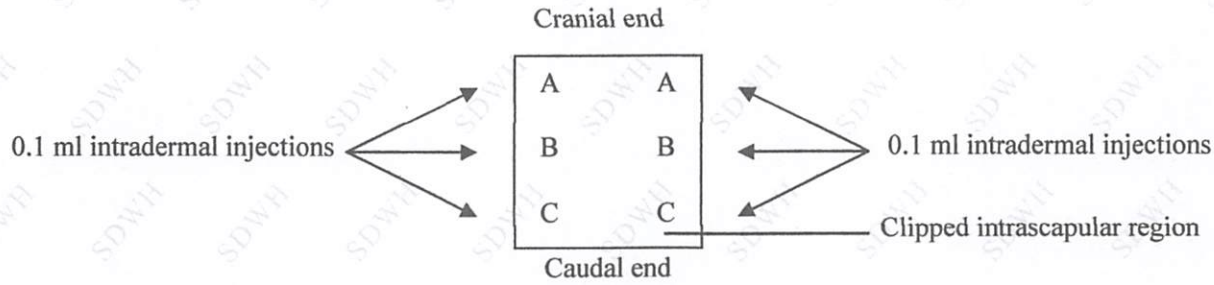


Figure 1 Location of intradermal injection sites

10.5 Topical induction phase Ⅱ

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Use the concentration selected in Intradermal induction phase Ⅰ for site B. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

10.6 Challenge phase

At 14 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a blank by topical application to sites that were not treated during the induction stage, using absorbent gauze (2.5cm×2.5cm) soaked in the test sample at the concentration selected in the intradermal induction phase Ⅰ for site C. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

10.7 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48 ±2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

10.8 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

10.9 Results

Individual results of dermal scoring for the challenge appear in Table 2.

10.10 Conclusion

Under the conditions of this study, the test article Powder Free Nitrile Examination Gloves extract showed no significant evidence of causing skin sensitization in the guinea pig.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

13.0 Deviation statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Test Group	1	0	0	0	0	0	0	0%
	2	0	0	0	0	0	0	
	3	0	0	0	0	0	0	
	4	0	0	0	0	0	0	
	5	0	0	0	0	0	0	
	6	0	0	0	0	0	0	
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	
Negative control	11	0	0	0	0	0	0	—
	12	0	0	0	0	0	0	
	13	0	0	0	0	0	0	
	14	0	0	0	0	0	0	
	15	0	0	0	0	0	0	

Table 3 Weigh change and Clinical observation

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Test Group	1	326	398	Normal
	2	347	431	Normal
	3	330	405	Normal
	4	328	399	Normal
	5	355	426	Normal
	6	340	412	Normal
	7	331	408	Normal
	8	355	436	Normal
	9	324	395	Normal
	10	336	410	Normal
Negative control	11	349	428	Normal
	12	333	406	Normal
	13	346	428	Normal
	14	358	439	Normal
	15	360	445	Normal

Table 4 Guinea pig Sensitization Dermal Reactions of Positive Group

Group	Animal Number	24±2h before phase II patch application		24±2 h following Challenge phase		48±2 h following Challenge phase		Positive rate after challenge phase
		Left	Right	Test sites	Control sites	Test sites	Control sites	
Positive Group	1	3	3	2	0	2	0	100%
	2	3	3	2	0	2	0	
	3	3	3	2	0	2	0	
	4	3	3	2	0	2	0	
	5	3	3	2	0	2	0	
Negative control	6	0	0	0	0	0	0	—
	7	0	0	0	0	0	0	
	8	0	0	0	0	0	0	
	9	0	0	0	0	0	0	
	10	0	0	0	0	0	0	

Note: The data of positive control come from SDWH-M201601724-1 (Completed Date: 2016-08-25)

Table 5 Weigh change and Clinical observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Positive Group	1	315	397	Normal
	2	322	400	Normal
	3	341	429	Normal
	4	323	408	Normal
	5	316	394	Normal
Negative control	6	310	397	Normal
	7	307	395	Normal
	8	321	413	Normal
	9	339	430	Normal
	10	314	395	Normal

Note: The data of positive control come from SDWH-M201601724-1 (Completed Date: 2016-08-25)

Test Report

No. NGBHG1702376301 Date: 31 May 2017

BLUE SAIL MEDICAL CO.,LTD

NO.21 QINGTIAN ROAD,QILU CHEMICAL INDUSTRIAL PARK,ZIBO CITY,SHANDONG PROVINCE,CHINA,255414

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

SGS Job No. :	QDHL1705011377OT - QD
Date of Sample Received :	24 May 2017
Testing Period :	24 May 2017 - 31 May 2017
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
FDA 21 CFR 177.2600- Total Extractives	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Ningbo Branch

Iris Xiao
Approved Signatory

SGS-CSTC Standards Technical Services Co.,Ltd. Ningbo Branch Chemical Laboratory

1-5/F West of Building 4, Lingyun Industry Park, No.1177 Lingyun Road, Ningbo National Hi-Tech Zone, Ningbo, Zhejiang, China 315040 t E&E (86-574)89070249 www.sgsgroup.com.cn
中国·浙江·宁波市国家高新区凌云路1177号凌云产业园4号楼西1-5层 邮编: 315040 t HL (86-574)89070271 t ML (86-574)89070242 e sgs.china@sgs.com

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	NGB17-023763.001	Purple-blue nitrile rubber glove	Nitrile rubber

FDA 21 CFR 177.2600- Total Extractives

Test Method : As specified in FDA 21 CFR 177.2600.

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001 Total Extractives
Distilled Water	7.0hr(s)	Reflux temperature	20mg/inch²	<0.5mg/inch²
Succeeding Extraction	2.0hr(s)	Reflux temperature	1mg/inch²	<0.5mg/inch²
n-Hexane	7.0hr(s)	Reflux temperature	175mg/inch²	0.9mg/inch²
Succeeding Extraction	2.0hr(s)	Reflux temperature	4mg/inch²	<0.5mg/inch²

Notes :

(1) hr = hour
(2) < = less than
(3) mg/inch² = milligram per square inch

1-5/F West of Building 4, Lingyun Industry Park, No.1177 Lingyun Road, Ningbo National Hi-Tech Zone, Ningbo, Zhejiang, China 315040 t E&E (86-574)89070249 www.sgsgroup.com.cn
中国·浙江·宁波市国家高新区凌云路1177号凌云产业园4号楼西1-5层 邮编: 315040 t HL (86-574)89070271 t ML (86-574)89070242 e sgs.china@sgs.com

Sample photo:

NGB17-023763.001

SGS authenticate the photo on original report only

*** End of Report ***

SGS-CSTC Standards Technical Services Co.,Ltd. Ningbo Branch Chemical Laboratory

1-5/F West of Building 4, Lingyun Industry Park, No.1177 Lingyun Road, Ningbo National Hi-Tech Zone, Ningbo, Zhejiang, China 315040 t E&E (86-574)89070249 www.sgsgroup.com.cn

中国·浙江·宁波市国家高新区凌云路1177号凌云产业园4号楼西1-5层 邮编: 315040 t HL (86-574)89070271 t ML (86-574)89070242 e sgs.china@sgs.com

Test Report No. 7191233436-EEC20/01-WBH
dated 13 Apr 2020

PSB Singapore

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

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 05 Mar 2020.

TESTED FOR:

Blue Sail Medical Co., Ltd.
Qilu Chemical Industrial Park,
No. 21 Qingtian Rd.,
255414, Zibo, Shandong,
China.

TEST DATE:

09 Mar 2020 to 09 Apr 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	BS 020-N01	Blue	01254511	XS	60	Blue Sail Medical Co., Ltd.
				01254512	S	60	
				01264711	M	60	
				01264712	L	60	
				01264921	XL	400	

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

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

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

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

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

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Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

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

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	1	Passed
		L		10	315	1	Passed
		XL		10	315	1	Passed

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

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	243	Passed
		S		13	246	Passed
		M		13	242	Passed
		L		13	242	Passed
		XL		13	250	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	84	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	10.8	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.9	Passed
		XL		13	10.8	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	9.6	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.3	Passed
		XL		13	10.8	Passed

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

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

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

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

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2019001		NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS	0.04 mg per glove	Passed
			S	0.17 mg per glove	Passed
			M	0.51 mg per glove	Passed
			L	0.14 mg per glove	Passed
			XL	0.18 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove		NA

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

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

PSB Singapore

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 04 Apr 2020.

2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2019001.

3. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

Test Report No. 7191233436-EEC20/03-WBH
dated 13 Apr 2020

PSB Singapore

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SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by Blue Sail Medical Co., Ltd. on 05 Mar 2020.

TESTED FOR:

Blue Sail Medical Co., Ltd.
Qilu Chemical Industrial Park,
No. 21 Qingtian Rd.,
255414, Zibo, Shandong,
China.

TEST DATE:

09 Mar 2020 to 09 Apr 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	BS 020-N03	Blue Purple	02153711	XS	60	Blue Sail Medical Co., Ltd.
				02163811	S	60	
				02153922	M	60	
				02164612	L	60	

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

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

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

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

TÜV SÜD PSB

Laboratory:
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Co. Reg : 199002667R

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

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	0	Passed
		L		10	315	1	Passed

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

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	240	Passed
		S		13	242	Passed
		M		13	248	Passed
		L		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	104	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.2	Passed
		S		13	6.6	Passed
		M		13	6.4	Passed
		L		13	6.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed
		S		13	6.9	Passed
		M		13	6.3	Passed
		L		13	6.9	Passed

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

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

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

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

Clause	Tests	Requirements	Results / Remarks		Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2019001		NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients		NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'		NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS	0.02 mg per glove	Passed
			S	0.06 mg per glove	Passed
			M	0.27 mg per glove	Passed
			L	0.24 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove		NA

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

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

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 04 Apr 2020.

2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2019001.

3. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

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4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park
No 21 Qingtian Road
Zibo
Shandong
China

This is to certify that the following products tested under SATRA reports referenced:CHM0291439/1944/JH & STE0289547 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11521-01/E00-00	BS01020X	Disposable medical Nitrile examination glove	EN ISO 374-1:016

Dated: 14th November 2019

This certificate is valid until: November 2020

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeurope.com

SATRA TECHNOLOGY

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park,
No 21 Qingtian Road
Zibo
Shandong
China

Notified Body: 2777

SATRA customer number: P1543

EU Type-Examination Certificate

Certificate number: 2777/11521-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:	**Description:**
	Disposable Medical Nitrile Examination Gloves Available in
BS010201	Blue
BS010202	Blue Purple
BS010203	Cobalt Blue
BS010204	White
BS010205	Black

Sizes: 6 – 10 (XS – XL)

Classification:

EN ISO 374-1:2016 /Type B	**Level**	**EN 374-4:2013 Degradation %**
40% Sodium Hydroxide (K)	6	-38.4
30% Hydrogen Peroxide (P)	2	17.6
n-heptane (J)	0	27.4
25% Ammonium hydroxide (O)	0	29.9
37% Formaldehyde (T)	5	46.6
EN ISO 374-5:2016	**Level**	
Protection against Bacteria and Fungi	Pass	
Protection against Viruses	Pass	

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

Technical reports/Approval documents:
SATRA: CHT0269325/1814, CHT0269325/1814/SPT, CHT0271193/1821/JS/A, CHT0271193/1821/JS/B, CHT0269325/1814/EN/A, CHT0269325/1814/EN/B, CHT0271193/1821/SPT, CHT0271193/1821, CHT0273567/1830/LH/B, CHT0275700/1838/LH, CHT0269325/1814/EN/C, CHT0275700/1838/LH

Signed on behalf of SATRA: Tara Saunders Austin Simmons

Date first issued: 09/11/2018
Date of issue: 09/11/2018

Expiry date: 09/11/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

EU DECLARATION OF CONFORMITY

Doc No.: D-MDR-02/08-A00

Identification of the Legal Manufacturer & Address	: Blue Sail Medical Co., Ltd : No. 21 Qingtian Road, Qilu Chemical Industrial Park, Zibo, Shandong 255414 China
European Authorized Representative	:Lotus NL B.V. : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands :Tel: +31 645171879 （English） +31626669008 (Dutch) :Email: peter@loutsnl.com
Basic UDI-DI	: Details please reference the Article 1.1 part (4) of the CE technical files.
Product & Identification	: **Disposable Nitrile Patient Examination Gloves**
Intended purpose of the product:	The Disposable Nitrile Patient Examination Gloves is a disposable Product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
GMDN code and product:	**56286 Nitrile examination/treatment glove, non-powdered, non-sterile** : Detail of product code, common specification please reference to Doc#: D-MDR-02/05-A00, Doc# D-MDR-02/02-A00 in the CE Technical Files.
Risk Classification:	: Class 1, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure	: Article 4.1 Rule 1, Non-invasive device, and/or : Article 5.1 intended for transient use, Rule 5 of invasive device of Annex VIII.
Conformity Route	: Self-Declaration
Relevant Harmonized Standards:	:EN ISO13485:2016 :EN 455-1: 2000, EN455-2:2015, EN455-3 2015 , EN455-4:2009 :EN ISO 374-1:2016, EN374-2: 2014, EN16523-1:2015, EN374-4:2013, ENISO 374-5: 2016, EN420: 2003+A1:2009
Certification Body	:TUV SUD PSB Singapore
Registration Date	: March 23, 2018
Registration No.	: 03855
Quality System Certificate	: Certificate No: Q5 062837 0012 Rev. 01 : Certificate Body: TUV SUD Product Service GmbH : Issued Date: Aug 1, 2019
Identification of the person authorized to sign on behalf of the Legal Manufacturer:	:Singed by:

Robin Liu

:Print Name: Robin Liu
:Title: Quality Director
:Place of Issue: Zibo, Shandong, China
:Date: 08/20/2019