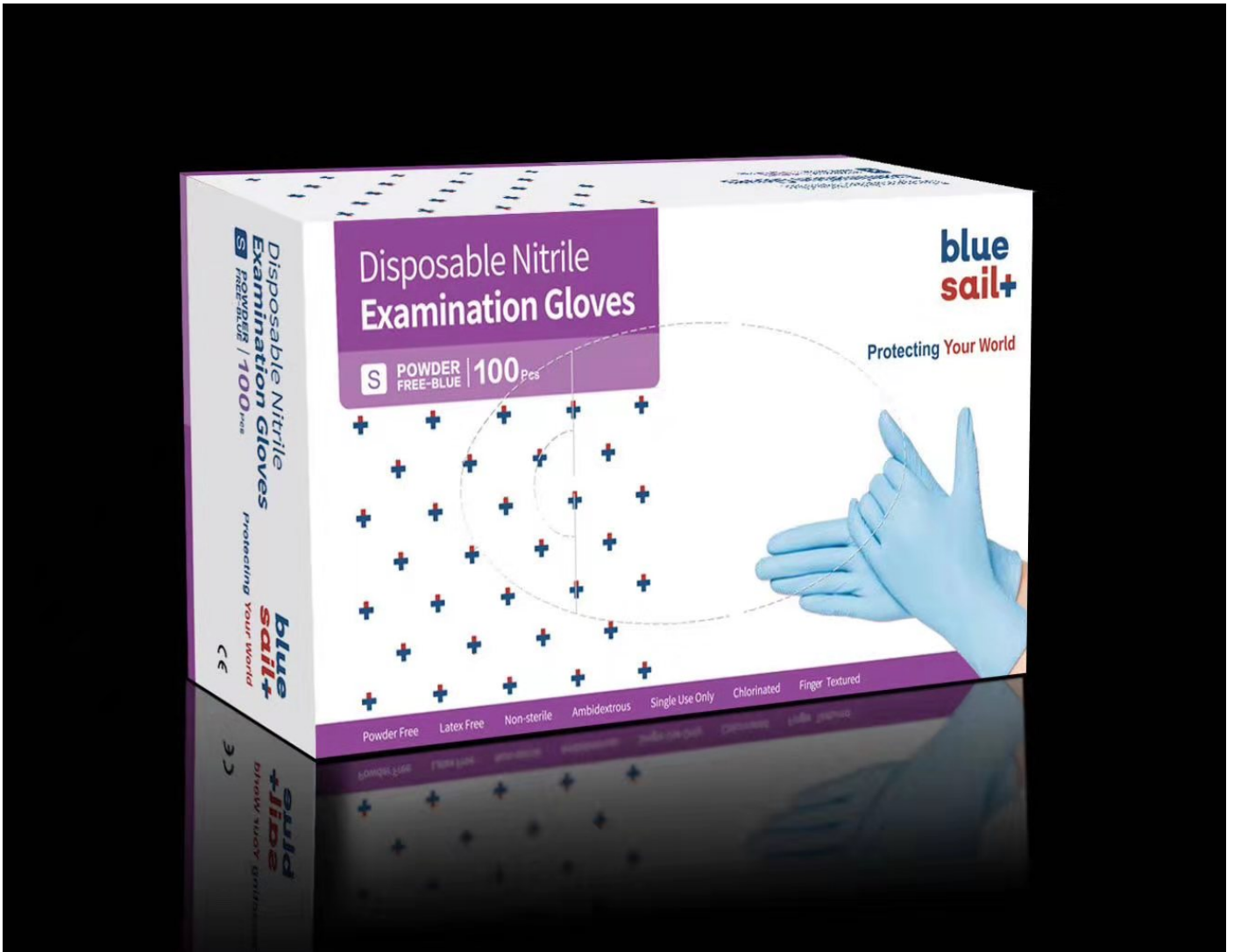


Zusatz Information



Zusatz Information



Zusatz Information



蓝帆医疗丁腈手套技术文件清单

- 生产厂家简介
- 产品图示
- 营业执照
- 医疗器械备案凭证
- ISO13485 认证
- 产品检测报告
- CE 认证
- 符合性声明

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。





品牌：

蓝帆医疗

品名：

一次性丁腈手套

材质：

丁腈化合物

尺寸：

XS/S/M/L/XL

类型：

无粉

长度：

9 寸

颜色：

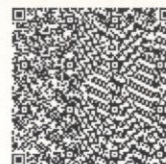
白色、蓝色、黑色、钴蓝色、蓝紫色



营业执照

(副本)

1-1



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'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

统一社会信用代码
91370000744521618L

名称 蓝帆医疗股份有限公司

注册资本 人民币 玖亿陆仟肆佰零叁万壹仟零捌拾陆元整

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%)

成立日期 2002年12月02日

法定代表人 刘文静

营业期限 2002年12月02日至 年 月 日

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。)

住所 山东省淄博市齐鲁化学工业区清田路21号

登记机关



2019年10月24日

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



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 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		

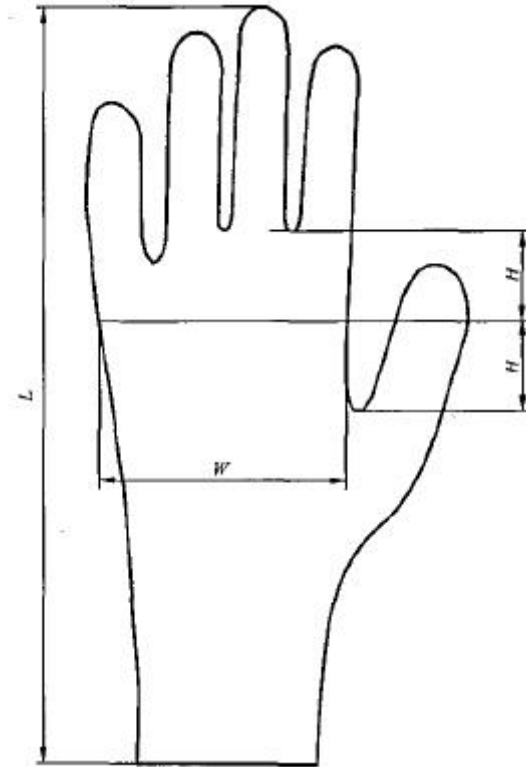
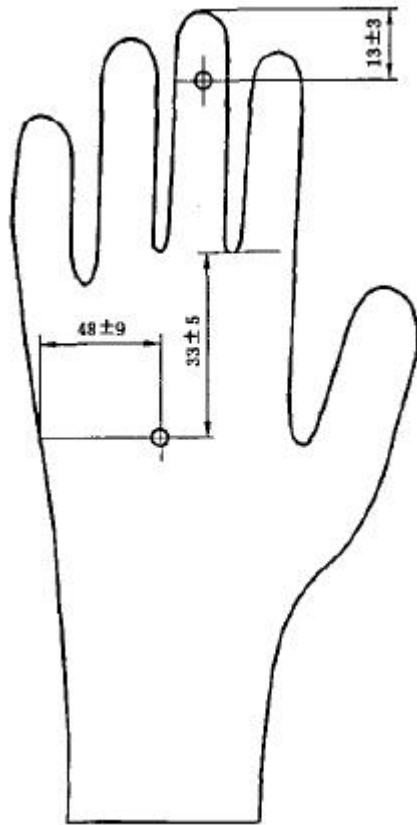


图 1 宽度和长度测量位置



注：对于不同规格的手套， $48\text{mm} \pm 9\text{mm}$ 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 $\geq 7.0\text{N}$;
2. 老化前扯断伸长率 $\geq 500\%$;
3. 老化后扯断力 $\geq 7.0\text{N}$;
4. 老化后扯断伸长率 $\geq 400\%$;
5. 有粉手套表面残余粉末含量不大于 $10\text{mg}/\text{dm}^2$ 。无粉手套表面残余粉末含量不大于 $2.0\text{mg}/\text{只}$ 。

【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】



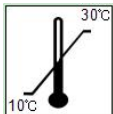
：本产品用于一次性使用



：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°C 到 30°C

【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

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



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

Phone : +65-6885 1333
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
TUV®

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	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	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

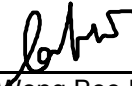
Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the 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

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

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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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-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



Laboratory:
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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
TUV®

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

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



PSB Singapore

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

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



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ZIBO BLUE SAIL PROTECTIVE PRODUCTS 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, BLUE

SGS Job No. : QDHL1902002781OT - QD
Item No. : M
Date of Sample Received : 18 Feb 2019
Testing Period : 18 Feb 2019 - 28 Feb 2019
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

Council of Europe Resolution AP (2004) 4 -Overall migration

PASS

Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine

PASS

Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances

PASS

Conclusion : The tested parameters comply with the requirement stated in Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004.

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



Wang Bo, Claire
Approved Signatory



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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TAO19-005885.001	Blue rubber gloves	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)

Council of Europe Resolution AP (2004) 4 -Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
EN 1186-9: 2002 aqueous food simulants by article filling method;
EN 1186-2: 2002 olive oil by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall Migration</u>	<u>Conclusion</u>
3% Acetic acid (W/V) aqueous solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS
10% Ethanol (V/V) aqueous solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS
Rectified olive oil	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²	PASS

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm² or 12 mg/kg.
- (2) Analytical tolerance of fatty food simulants is 3 mg/dm² or 20mg/kg.
- (3) Test condition & simulant were specified by client.
- (4) The test data is obtained by considering the articles intended for repeated use as per described in Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex V. Report the 3rd extractive result.
- (5)The rectified olive oil simulant test was subcontracted to SGS Shanghai chemical lab.

Council of Europe Resolution AP (2004) 4 -Specific migration of primary aromatic amine

Test Method : With reference to EN 13130-1: 2004, analysis was performed by UV-Vis.



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Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
 Test Condition : 40°C 2.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of primary aromatic amine	0.01	mg/kg	0.01	ND
Conclusion				PASS

Notes :

- (1)Test condition & simulant were specified by client.
- (2)The test was subcontracted to SGS Shanghai chemical lab.

Council of Europe Resolution AP (2004) 4 -Specific migration of nitrosamine and nitrosatable substances

Test Method : With reference to EN 13130-1: 2004, analysis was performed by GC-MS.

Sample 001

Simulant Used : 3% Acetic acid (W/V) aqueous solution
 Test Condition : 40°C 2.0hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of Nitrosamines	0.01	mg/kg	0.01	ND
Specific migration of Nitrosatable substances	0.1	mg/kg	0.1	ND
Conclusion				PASS

Notes :

- (1) Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBzA), N-nitroso-N-methyl-N-phenylamine (NMPHA), N-nitroso-N-ethyl-N-phenylamine (NEPhA), N-nitrosodiisononylamine (NDiNA) and N-Nitrosodiisobutylamine (NDiBA)
- (2) Test condition & simulant were specified by client.
- (3)The test was subcontracted to SGS Shanghai chemical lab.



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Sample photo:



TAO19-005885.001

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*** End of Report ***



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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



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



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:

BS010201
BS010202
BS010203
BS010204
BS010205

Disposable Medical Nitrile Examination Gloves
Available in
Blue
Blue Purple
Cobalt Blue
White
Black

Sizes: 6 – 10 (XS – XL)

Classification:

EN ISO 374-1:2016 /Type B

40% Sodium Hydroxide (K)
30% Hydrogen Peroxide (P)
n-heptane (J)
25% Ammonium hydroxide (O)
37% Formaldehyde (T)

Level EN 374-4:2013 Degradation %

6	-38.4
2	17.6
0	27.4
0	29.9
5	46.6

EN ISO 374-5:2016

Protection against Bacteria and Fungi
Protection against Viruses

Level
Pass
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

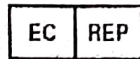
Doc No.: D-MDR-02/08-A00

**Identification of the Legal
Manufacturer & Address**



: Blue Sail Medical Co., Ltd
: No. 21 Qingnian Road, Qilu Chemical Industrial Park,
Zibo, Shandong 255414 China

**European Authorized
Representative**



: Lotus NL B.V.
: Koningin Julianaplein 10, Le Verd, 2595 AA, The Hague,
Netherlands
: Tel: +31 645171879 (English) +31626669008 (Dutch)
: Email:

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:

S6286 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 I, 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 ISO 13485:2016
: 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: QS 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:**

: Signed by:

Robin Liu

: Print Name: Robin Liu

: Title: Quality Director

: Place of Issue: Zibo, Shandong, China

: Date: 08/20/2019