



blue
sail+
蓝帆医疗

GAUKE Healthcare

高德救护

Introduction

企业介绍

Gauke Healthcare was established in 2003, located in Huanggang city Hubei province, integrating research and development, production and sales of medical device and PPE. After years of development, it has become a leader in the field, and was merged into the listed company Bluesail in 2016, laying a foundation for the company's further development.

Since the outbreak of the coronavirus, the company has invested a lot of funds to buy, adjust and transform the existing production lines, expand the production of epidemic materials, and support anti-epidemic work.

高德救护成立于2003年，位于湖北省黄冈市，集医疗器械、个人防护用品研发、生产和销售一体。经过多年发展成为急救包行业的领导者，并在2016年并入上市公司蓝帆医疗，为公司进一步发展奠定了基础。

在疫情发生以来，公司投入大量资金，对现有产线进行调整、改造，扩大疫情物资生产，支持抗疫工作。

Product Introduction

产品介绍

Vinyl Examination Gloves
PVC 检查手套



Nitrile Examination Gloves
丁腈检查手套



Nitrile Gloves
丁腈工业手套



Disposable Medical Face Mask
一次性防护口罩



Disposable Medical Face Mask
KN95 防护口罩



First Aid Kit 防疫包





Workshop

车间展示







Report 检测报告

Test Report No. 7191179419-EEC18-CSL
dated 23 Mar 2018



PSB Singapore

Choose certainty
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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 25 Jan 2018 and 06 Mar 2018.

TESTED FOR:

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

TEST DATE:

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	121505111		100	Blue Sail Medical Co., Ltd.
				030805111	XS	69	
				121505211	S	100	
				120803111	M	100	
				120804111	L	100	
				120709111	XL	407	

Lot size as specified by client: 200,000 pieces

METHOD OF TEST:

- EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



Laboratory:
TUV SUD PSB Pte Ltd
No. 1 Science Park Drive
Singapore 118221

Phone: +65-6885 1333
Fax: +65-6778 9070
Email: enquiries@tuv-sudpsb.sg
www.tuv-sudpsb.sg
Co. Reg: 19902027R

Regional Head Office:
TUV SUD Asia Pacific Pte Ltd
1 Science Park Drive, #C2-01
Singapore 118221
TUV

Test Report No. 7191227746-EEC20-WBH
dated 22 Jan 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 Gloves submitted by Blue Sail Medical Co., Ltd on 11 Dec 2019.

TESTED FOR:

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

TEST DATE:

11 Dec 2019 to 17 Jan 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Powder-Free Examination Gloves	BS 015-02	Clear	11294312	XS	50	Blue Sail Medical Co., Ltd
				11294111	S	60	
				11294222	M	60	
				11295511	L	60	
				11255611	XL	400	

Lot size: 150,001 to 500,000 pieces

METHOD OF TEST:

- EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
- EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
- EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



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Singapore 118221
TUV



SHENZHEN CCT TESTING TECHNOLOGY CO., LTD. NO.: CCT20031808PRS

TEST REPORT

Prepared For :	GAUKE Healthcare Co., Ltd Chengnan Industrial Park,TuanFeng County, Huang Gang city ,Hubei province China
Trade Mark :	N/A
Product Name :	medical mask
Model(s) :	Non woven 3ply
Prepared By:	Shenzhen CCT Testing Technology Co., Ltd. 8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China Tel: +86 755-3315 7675 Fax: +86 755-33609691 Email: cct@cct-prc.com Web: www.cct-prc.com
Test Date:	Mar. 18, 2020 - Mar. 23, 2020
Date of Report:	Mar. 23, 2020
Report No. :	CCT20031808PRS

Note: This test report is limited to the above client company and the product model only. It may not be duplicated without prior written consent of Shenzhen CCT Testing Technology Co., Ltd.



SHENZHEN CCT TESTING TECHNOLOGY CO., LTD. NO.: CCT20031808PRS

PPE Technical Paper Report

Prepared For :	GAUKE Healthcare Co., Ltd Chengnan Industrial Park TuanFeng County HuangGang Hubei China
Trade Mark :	N/A
Product Name :	Face Mask
Model(s) :	KN95



Date: 20200328

Shenzhen CCT Testing Technology Co., Ltd.

8th Floor, Area I, Building 1, Hanhaida Science and Technology Innovation Park, Guangming New District, Shenzhen, Guangdong, China
Tel: +86 755-3315 7675 Fax: +86 755-33609691
Email: cct@cct-prc.com Web: www.cct-prc.com

Certifications

资质





Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60145757 0001
Report No.: 15091167 009

Manufacturer: GAUKE Healthcare Co., Ltd.
Chengnan Industrial Park
Tuanfeng County
HuangGang
438800 Hubei
P.R. China

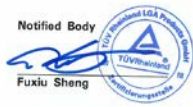
Products:

Medical Gauze Swabs/Lap Sponges/Gauze Balls with
X-ray Detectable;

Aspects of manufacture concerned with securing and
maintaining sterile conditions;

Medical Gauze Swabs /Gauze Balls, Absorbent Cotton
Rolls/Cotton Balls/Cotton Pads/Gauzes, Sterile Non-woven
Sponges/Balls, First Aid Kits, Sterile Bandages, Sterile
Dressings, Wound Plasters

Date: 2020-02-24



2020

CERTIFICATE OF REGISTRATION

This certifies that:

GAUKE HEALTHCARE CO., LTD.
Chengnan Industrial Park
Tuanfeng County
HuangGang Hubei, CHINA 438800

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration: 3006362781
Device Classification Name: MASK, SCAVENGING
Product Code: KHA
Regulation Number: 868.5590
Official Correspondent and U.S. Agent: Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lenarz
Executive Director
Registrar Corp
Dated: December 2, 2019



对外贸易经营者备案登记表

备案登记编号: 03027335

统一社会信用代码: 9142910355843596XL
进出口企业代码: _____

经营者中文名称	武汉必凯尔救助用品有限公司		
经营者英文名称	GAUKE INTERNATIONAL TRADING CO.,LTD		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	私营有限责任公司
住 所	武汉市江阳区青年路66-5号招银大厦407室		
经营场所 (中文)	武汉市江阳区青年路66-5号招银大厦407室		
经营场所 (英文)	SUITE407 CHINA MERCHANTS BANK PLAZA NO.66-5 QINGNIAN ROAD,JIANGHAN DISTRICT WUHAN CHINA		
联系电话	027-84803213	联系传真	027-84803467
邮政编码	430050	电子邮箱	2356859522@qq.com
工商登记注册日期	2010-8-19	工商登记注册号	_____

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	隋建勋	有效证件号	420103196406124418
注册资金	壹仟捌佰肆拾伍元零肆 零玖万元		(折美元)

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

企业法定代表人/ 个体工商户负责人姓名		有效证件号	
企业资产/个人财产			(折美元)

备注	
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填表前请认真阅读背面的条款,并由企业法定代表人或个体工商户负责人签字、盖章。



2017 年 02 月 07 日