



# 营业执照

(副本) (1-1)

统一社会信用代码 9142900475703865X7

名称 仙桃市保康防护用品有限责任公司  
 类型 有限责任公司(自然人投资或控股)  
 住所 仙桃市龙华山办事处青鱼湖路(第二制药厂内)  
 法定代表人 孙冬梅  
 注册资本 壹佰万圆整  
 成立日期 2004年03月03日  
 营业期限 长期  
 经营范围 塑料制品、无纺布制品、纸制品、一次性卫生制品的加工、销售；货物进出口、技术进出口(法律、行政法规禁止的项目除外；法律、行政法规限制的项目取得许可后方可经营)。

此报告仅限于阅读存档



登记机关



2018年11月13日

File No: CE-TCF-001



**EC Declaration of Conformity**



**Regarding Medical Device Directive(93/42/EEC)  
including Directive 2007/47/EC**

**Manufacturer**

Name: Baokang Protection Products Co.,Ltd.

Address: 16TH QINGYUHU ROAD, THE OFFICE OF LONGHUASHAN, XIANTAO,  
HUBEI, CHINA.

**Product**

Name: Face Masks, Caps, Isolation Gowns, Surgical Gowns, Lab Coat, Coveralls, Aprons,  
Beard Covers, Shoe Covers, Boot Covers, Sleeve Covers, Gloves, Triangle Bandage, Bed  
Sheets, Pillow Cases.

Type: See Annex of details

Classification: I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2012

EN 1041:2008

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Signature:



Date:

2017-01-16

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## Annex to Report (No. 02656 )

Baokang Protection Products Co.,Ltd.

Product Name	Type
Face Masks	Number of plies:1-ply, 2-ply, 3-ply, 4-ply, 5-ply; Type: ear-loop, tie on, cup mask(With valve /Without valve), paper face mask ; Size:(12.5cm*8cm), (14.5*9.5cm), (17.5*9.5cm) (21*9.5cm),etc.
Caps	(18" 19" 21"24"), strip-type (Single elastic Double elastic), round type, tie-on type
Isolation Gowns	S, M, L, XL, XXL, XXXL, XXXXL
Surgical Gowns	S, M, L, XL, XXL, XXXL, XXXXL
Coveralls	S, M, L, XL, XXL, XXXL, XXXXL
Aprons	S, M, L, XL, XXL, XXXL, XXXXL
Lab Coat	S, M, L, XL, XXL, XXXL, XXXXL
Beard Covers	9-20g, 16"-21"
Shoe Covers	(15cm-20cm)*(36cm-48cm) 1.5g--55g
Sleeve Covers	(16cm-25cm)*(36-50cm).
Bed Sheets	PP, SMS, PP+PE
Pillow Cases	PP, SMS, PP+PE
Triangle Bandage	96cmx96cmx136cm, 36"x36"x 51"
Boot Cover	S, M, L, XL, 48cm*38cm, 48cm*42cm
Gloves	S, M, L, XL

This annex is only valid if attached to the report mentioned above.



## Compliance Report

**Applicant:** Baokang Protection Products Co.,Ltd.  
**Address:** 16TH QINGYUHU ROAD, THE OFFICE OF  
LONGHUASHAN, XIANTAO, HUBEI, CHINA.

**Product:** Face Masks, Caps, Isolation Gowns, Surgical Gowns, Lab  
Coat, Coveralls, Aprons, Beard Covers, Shoe Covers, Boot  
Covers, Sleeve Covers, Gloves, Triangle Bandage, Bed Sheets,  
Pillow Cases.

**Type:** See annex for details

**Product Classification:** Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02656

Initial Issue Date: 24 Jan 2017

General Manager (Signature)



This is to certify that the Quality Management System of

**Baokang Protection Products Co., Ltd.**

Unified Social Credit Code : 9142900475703865X7

Operation Address : Inside of No.2 pharmaceutical factory, Qingyuhu Road, Huashan Office, Xiantao City, Hubei Province, China

Registered Address : Inside of No.2 pharmaceutical factory, Qingyuhu Road, Huashan Office, Xiantao City, Hubei Province, China

applicable to  
**此报告仅限于阅读存档**

Production and sales of non sterilized disposable non-woven fabric(masks, clothes, oversleeve, hats, shoe covers)(export to USA and EU)

has been assessed and registered by NQA against the provisions of

**ISO 13485: 2003**

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

*M Comsty*

Managing Director



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Certificate Number **44662**

Date: 12 April 2018

Valid Until: 12 April 2021

EAC Code: 19



# 检验检测报告

(电子版)

防伪查询网址：[www.gttc.net.cn](http://www.gttc.net.cn)

防伪码：GKVA-4273-14

共3页 第1页

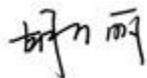


No:200027416



委托单位	仙桃市保康防护用品有限责任公司 地址：仙桃市龙华ft办事处青鱼湖路（第二制药厂内）		
客户认定信息	一次性口罩 12个 颜色：兰色		
检验性质	委托检测	样品受理/测试开始日期	2020-03-02
		报告签发日期	2020-03-05
判定依据	YY/T 0969-2013 《一次性使用医用口罩》		
	<b>此报告仅限于阅读存档</b>		
综合检验结论	---		
检验检测结果	检验检测项目	判定依据	判定
	细菌过滤效率	YY/T 0969-2013	符合
备注	本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号。		

签发：胡万丽 工程师

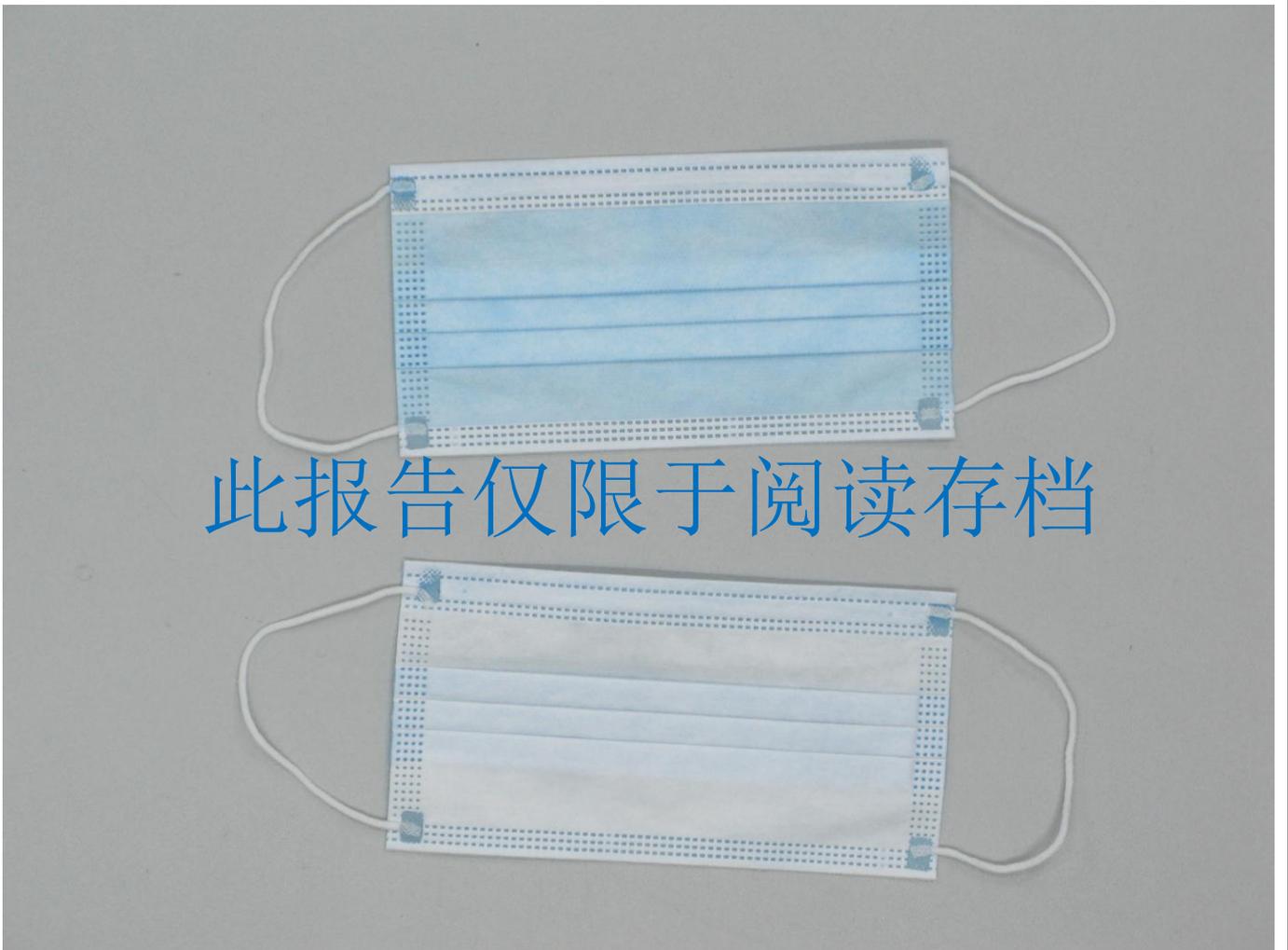


# 样品图片

(电子版)

No:200027416

共3 页 第2页



## 检验检测报告附页 (电子版)

No:200027416

共3页 第3页

检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●细菌过滤效率 (%)	YY 0469-2011 附录B 测试菌种: 金黄色葡萄球菌ATCC 6538 测试面积: 40cm 气体流速: 28.3L/min 平均颗粒直径: 3.0 μm 阳性质控值: 1.9×10 <sup>6</sup> CFU 阴性质控值: <1CFU	≥95	BFE 99.7 BFE 99.7 BFE 99.6	符合	
备  注	(本栏空白)				

50pcs/ small box



**Packing:**

One carton contains 40 small boxes

One carton total 2000pcs

Carton size: 58×38×30cm

