



## 关于东之星

- 1.公司获得一类医疗器械生产备案凭证,放心生产。
- 2.产品获得第一类医疗器械备案凭证,出口三证齐全。
- 3.产品通过GB14866-2006、EN166:2001、ANSI Z87.1检测认证 ,内销外销均可,出口欧美无忧。
- 4.公司获得CE/NB 欧盟检测报告.欧盟进口报关无忧。
- 5.公司获得FDA认证,通过CPSIA /CA65检测,美国进口报关无忧。
- 6.公司通过第三方权威机构验厂, 获得ISO 9001、BSCI认证, 大客户必备条件。
- 7.公司有进出口经营权、商检备案资质,和大规模易配合货代公司合作, 有自己的报关行, 用我司抬头报关, 有多次通关经验, 可包清关。
- 8.30条产线, 千人工厂, 日产百万, 交期保证。



- 1.Trustworthy factory with Class 1 Medical Device Production Record Certificate
- 2.Class 1 Medical Device Record Certificate and export license
- 3.Executive standard: GB14866-2006, EN166:2001, ANSI Z87.1, qualified for domestic sales and export
- 4.CE/NB Certificates, qualified for export to Europe
- 5.FDA, CPSIA/CA65 certificates, qualified for export to US
- 6.Pass audits by the professional third-party testing organization, ISO9001,and BSCI, qualified for big customers' order.
- 7.Company has been granted import-export rights and commodity inspection certificate; working with large logistic company use own broker; rich experiences of custom clearance
- 8.30 production lines, over one thousand workers, daily output 1 million pieces. Production time is guaranteed.

# 公司规模

## Production Site



# 包装展示 / Packaging Details(option 1)



33CM



22CM



产品名称：医用隔离面罩

产品型号：EST02094

款式：双面防雾

镜片材质：PET

海关编码 HS Code：3926909090

Product Name: Face shield

Model: EST02094

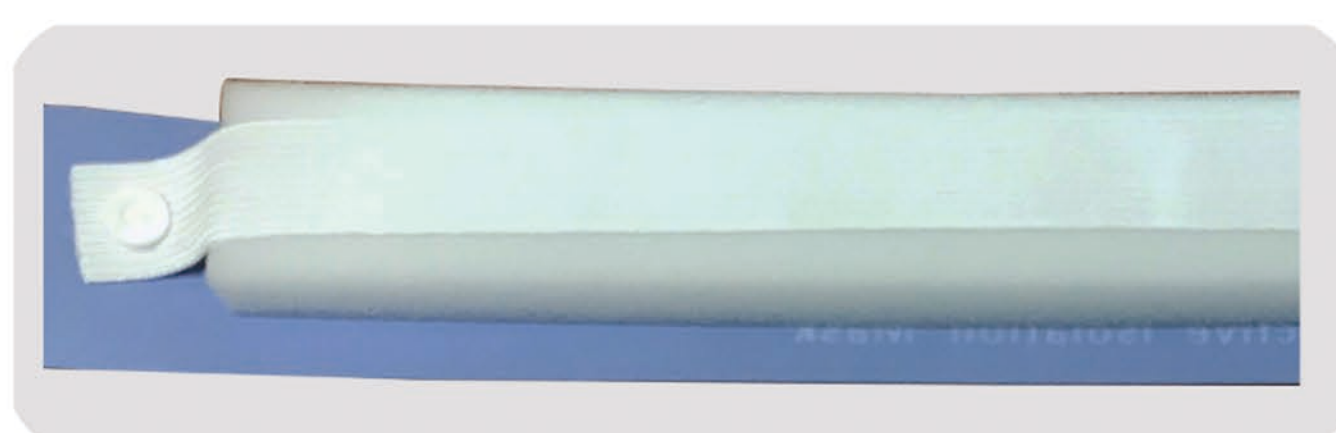
Style:Double-sided Anti-fog

Material for visor:PET

# 实拍细节 / Details Show

Warning:  
Use only as a face shield  
to prevent fluid splashing

**Face shield**  
Protective Isolation Mask



## ► CE,FDA,ISO9001 认证

CE,FDA,ISO9001 Certified

## ► 产能：100 万套/天

Production Capacity: 1 million pcs/day

## ► 执行标准 Carried Standard:GB 14866-2000/EN166:2001/ ANSI/ISEA Z87.1

# 包装展示/

## Pacaging Details(option 1)



| 箱 规 尺 寸 |              |
|---------|--------------|
| 单个尺寸    | 33*22CM      |
| 单个重量    | 30g          |
| 单只包装    | PE袋          |
| 单箱数量    | 240个         |
| 外箱尺寸    | 77x34x33CM   |
| 整箱重量    | 8.5KG        |
| 海绵垫尺寸   | 22x3.5x2.5CM |
| 松紧带尺寸   | 33*2CM       |



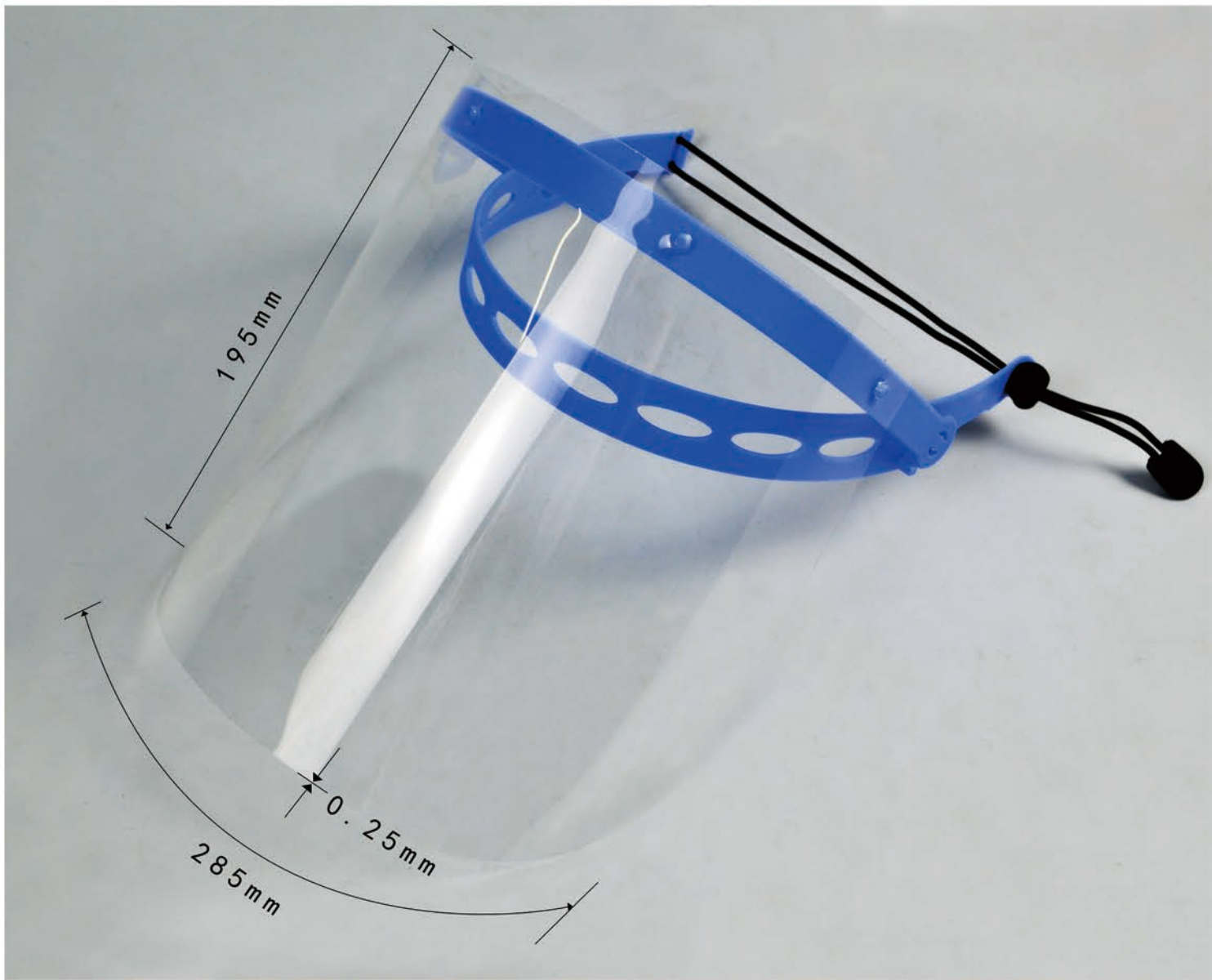
| 箱 规 尺 寸 |              |
|---------|--------------|
| 单个尺寸    | 33*22CM      |
| 单个重量    | 30g          |
| 十只包装    | PE袋          |
| 单箱数量    | 400个         |
| 外箱尺寸    | 68x37x38CM   |
| 整箱重量    | 14.5KG       |
| 海绵垫尺寸   | 26*3.3*1.6CM |
| 松紧带尺寸   | 33*2CM       |



| 箱 规 尺 寸 |              |
|---------|--------------|
| 单个尺寸    | 33*22CM      |
| 单个重量    | 30g          |
| 彩盒包装    | 20个          |
| 单箱数量    | 360个         |
| 外箱尺寸    | 75x35.5x34CM |
| 整箱重量    | 14KG         |
| 海绵垫尺寸   | 26*3.3*1.6CM |
| 松紧带尺寸   | 33*2CM       |

可调节医用隔离面罩

Face shield

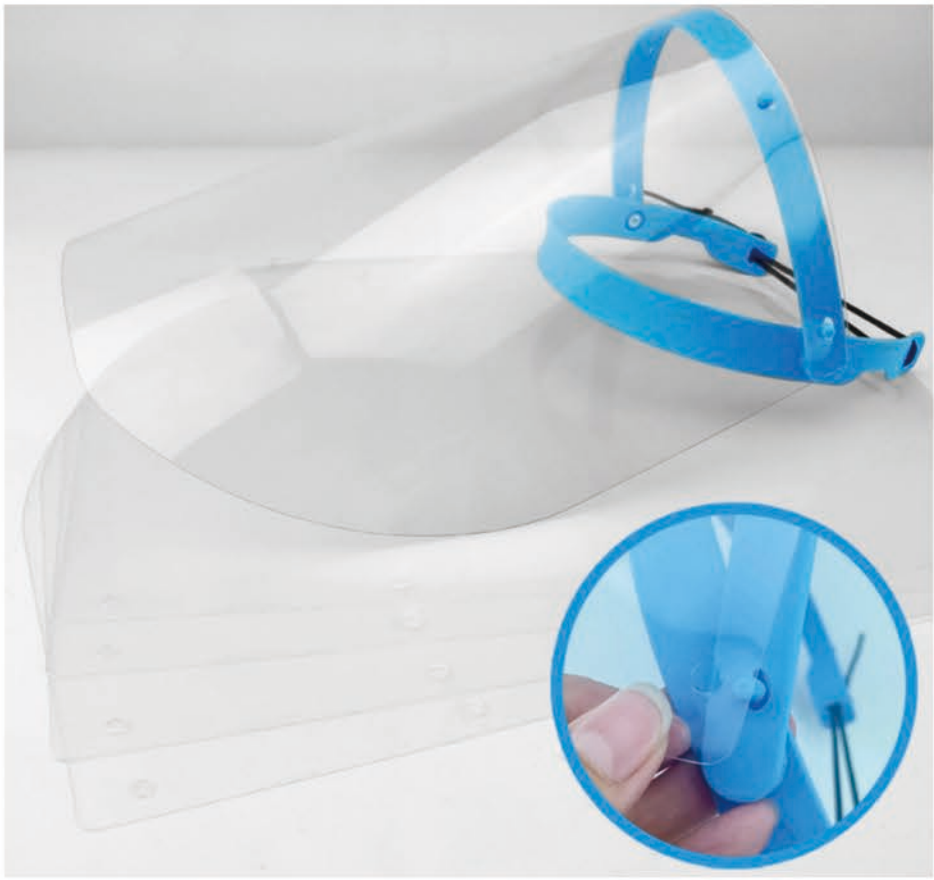


产品名称：医用隔离面罩  
产品型号：EST02103  
款式：双面防雾  
镜片材质：PET  
海关编码 HS Code：3926909090

Product Name: Face shield  
Model: EST02103  
Style:Double-sided Anti-fog  
Material for visor:PET

包装展示/

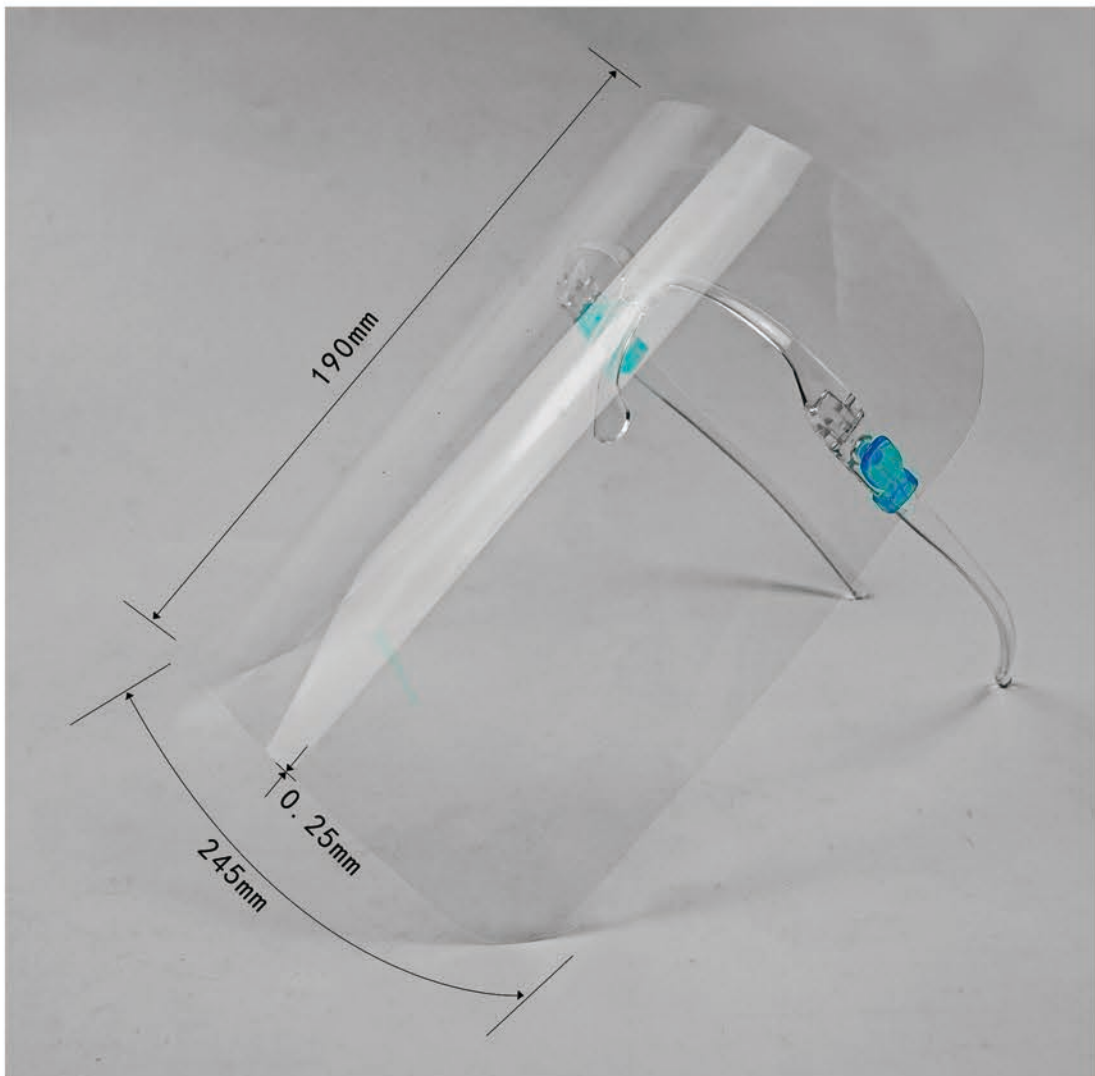
Packaging Details



| 箱 规 尺 寸 |            |
|---------|------------|
| 单个尺寸    | 28x19CM    |
| 单个重量    | 45g        |
| 单只包装    | PE袋        |
| 单箱数量    | 160个       |
| 外箱尺寸    | 59x49x53CM |
| 整箱重量    | 8.6KG      |

# 眼镜款隔离面罩

face shield with glasses



产品名称：眼镜款隔离面罩  
产品型号：EST02104  
款式：双面防雾  
镜片材质：PET  
海关编码 HS Code：9004909000

Product Name: Face shield  
Model: EST02104  
Style:Double-sided Anti-fog  
Material for visor:PET

## 包装展示/ Packaging Details

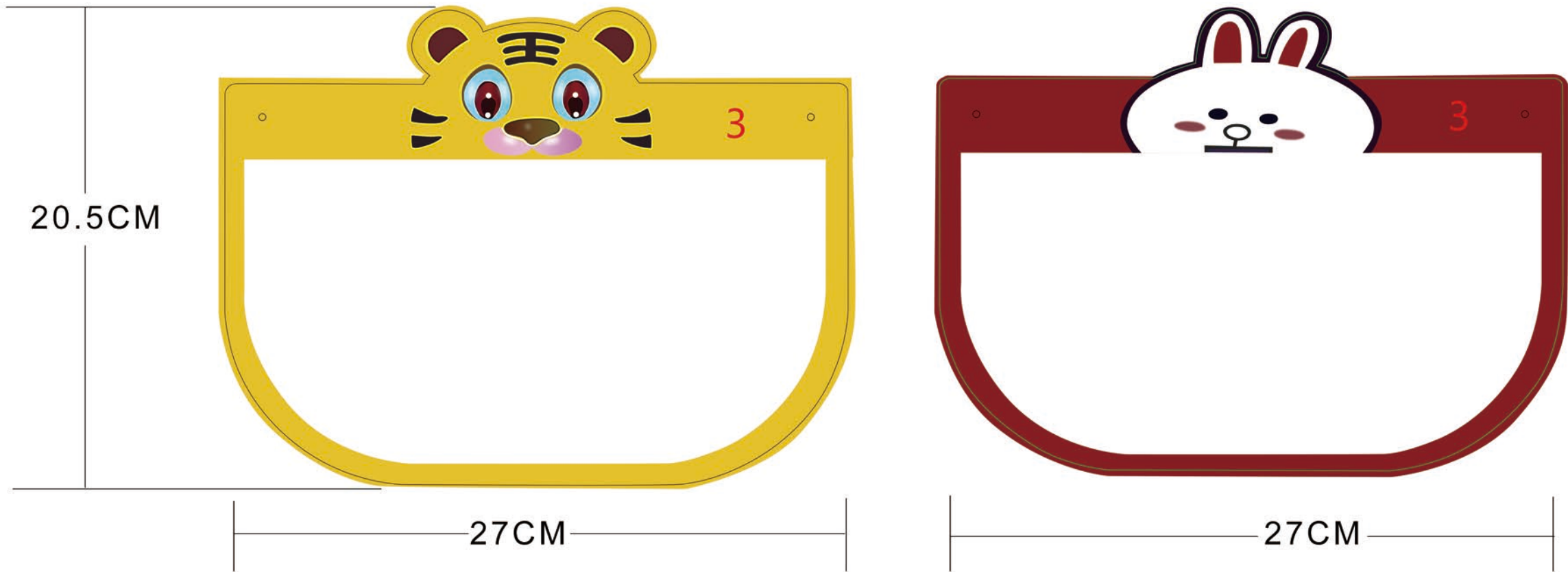


吸塑卡包装

| 箱 规 尺 寸 |             |
|---------|-------------|
| 单个尺寸    | 20.5*27 CM  |
| 单个重量    | 13.5 g      |
| 单只包装    | PE袋         |
| 单箱数量    | 400 个       |
| 外箱尺寸    | 62*56*40 CM |
| 整箱重量    | 8.6KG       |

# 儿童款隔离面罩

face shield kids



产品名称：儿童款隔离面罩  
产品型号：EST02098  
款式：双面防雾  
镜片材质：PET  
海关编码 HS Code：9004909000

Product Name: Face shield  
Model: EST02098  
Style:Double-sided Anti-fog  
Material for visor:PET

## 包装展示/ Packaging Details



| 箱 规 尺 寸 |            |
|---------|------------|
| 单个尺寸    | 20.5*27CM  |
| 单个重量    | 13.5g      |
| 单只包装    | PE袋        |
| 单箱数量    | 400个       |
| 外箱尺寸    | 62*56*40CM |
| 整箱重量    | 8.6KG      |

# 医用护目镜

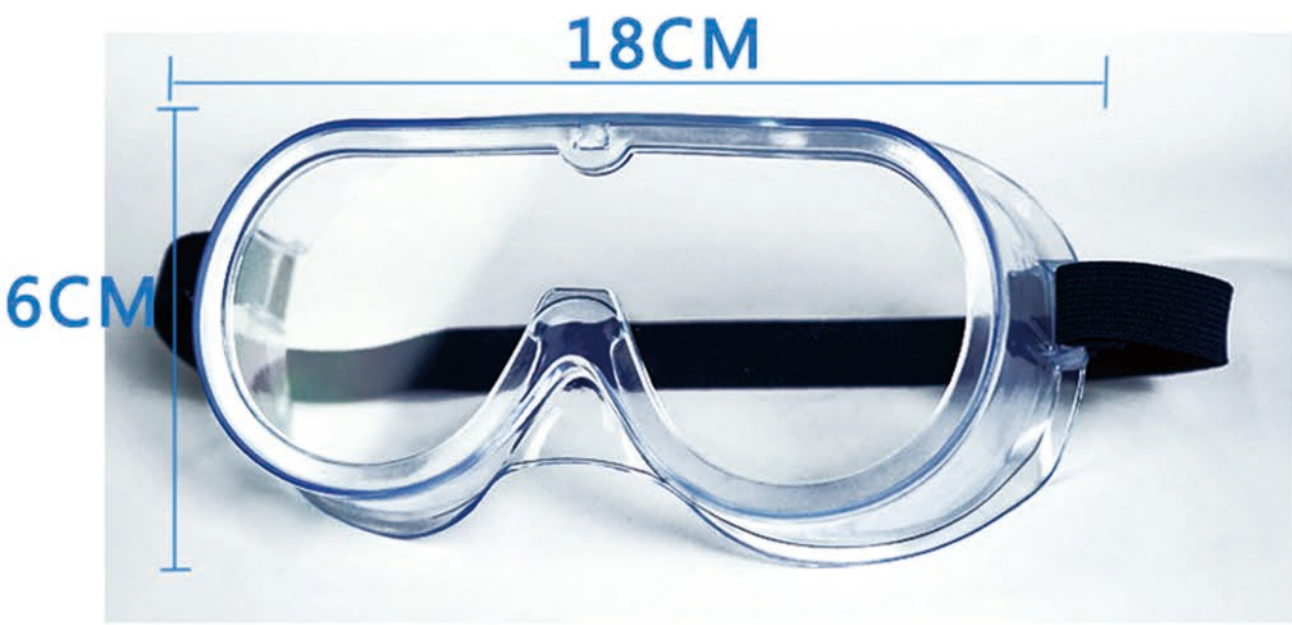
Safety goggle



EST02095



EST02100



EST02096



EST02097

产品名称：医用隔离护目镜  
产品型号：EST02095/EST020100  
EST02096/EST02097  
款式：双面防雾  
镜片材质：PVC+PC  
海关编码 HS Code：9004909000

Product Name: Safety Goggle  
Model: EST02095/EST020100  
EST02096/EST02097  
Style:Double-sided Anti-fog  
Material for visor:PVC+PC

## Details Show

实拍细节



# 包装展示

Packaging Details



单支袋包装



15只一内盒



外包装

## Qualification certificate

| 第一类医疗器械备案信息表         |                                                                |
|----------------------|----------------------------------------------------------------|
| 备案号: 粤深械备 20200270 号 |                                                                |
| 备案人名称                | 深圳市东之星电子科技有限公司                                                 |
| 统一社会信用代码             | 91440300MA5G03Q88                                              |
| 备案人注册地址              | 深圳市宝安区沙井街道共和社区第一工业区A区26栋二层                                     |
| 生产地址                 | 深圳市宝安区沙井街道共和社区第一工业区A区26栋二层                                     |
| 产品名称                 | 医用隔离面罩                                                         |
| 型号/规格                | EST02094, EST02098, EST02099, EST02102, EST02103               |
| 产品描述                 | 由高分子材料制成的防护罩、海绵条和固定装置组成。非无菌提供, 一次性使用。                          |
| 预期用途                 | 用于医疗机构中检查治疗时起防护作用, 阻隔体液, 血液飞溅或泼溅。                              |
| 备注                   |                                                                |
| 备案单位和日期              | 深圳市市场监督管理局<br>备案日期: 2020 年 4 月 3 日                             |
| 变更情况                 | 2020 年 6 月 22 日: 增加新型号 EST02098, EST02099, EST02102, EST02103。 |

| 第一类医疗器械备案信息表        |                                                                                                                                             |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 备案号：粤深械备 20200286 号 |                                                                                                                                             |
| 备案人名称               | 深圳市东之星电子科技有限公司                                                                                                                              |
| 统一社会信用代码            | 91440300MA5G03TQ8B                                                                                                                          |
| 备案人注册地址             | 深圳市宝安区沙井街道共和社区第一工业区 A 区 26 栋二层                                                                                                              |
| 生产地址                | 深圳市宝安区沙井街道共和社区第一工业区 A 区 26 栋二层                                                                                                              |
| 产品名称                | 医用隔离罩单                                                                                                                                      |
| 型号/规格               | EST02095, EST02096, EST02097, EST02100, EST02101                                                                                            |
| 产品描述                | 由高分子材料制成的防护罩和固定装置组成, 非无菌提供, 一次性使用。                                                                                                          |
| 预期用途                | 用于医疗机构中检查治疗时起防护作用, 阻隔体液、血液飞溅或飞溅。                                                                                                            |
| 备注                  |                                                                                                                                             |
| 备案单位<br>和日期         | <div>深圳市市场监督管理局</div> <div>备案日期: 2020 年 4 月 9 日</div>  |
| 变更情况                | 2020 年 6 月 22 日; 增加新型号 EST02097, EST02100, EST02101。                                                                                        |



# 国家药品监督管理局

## National Drug Supervision Administration

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产品地位

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[国产器械（历史数据）](#)  
[国产医疗器械产品（备案）](#)  
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[进口器械（历史数据）](#)  
[进口医疗器械产品（备案）](#)  
[医疗器械标准目录](#)  
[体外诊断试剂的分类目录（2013版）](#)  
[医疗器械临床中心器械目录](#)  
[医疗器械分类目录](#)  
[医疗器械生产企业（许可）](#)  
[医疗器械生产企业（备案）](#)  
[医疗器械经营企业（许可）](#)  
[医疗器械经营企业（备案）](#)

快速检索
高级检索

医疗器械

国产医疗器械产品（备案）

查询

备案号

备案人名称

产品名称

国产医疗器械产品（备案）
资料

备案号 粤海械备20200270号

备案人名称 深圳市车之东电子科技有限公司

备案人注册地址 广东省深圳市宝安区沙井街道共和社区第一工业区A区A26栋2层

生产地址 广东省深圳市宝安区沙井街道共和社区第一工业区A区A26栋2层

产品名称 医用精密泵

型号规格 型号：EST02094 规格：33\*22cm

产品描述 由高分子材料制成的仿生理、海陆空和真空驱动组成。无需充电，一次性使用。

预期用途 用于医疗器械的临床检查时辅助给药作用，超纯水、血液飞溅或飞溅。

备注

备案单位 深圳市市场监督管理局

备案日期 2020-04-03

更新情况

产品注册有效情况 /

注 网站发布的医疗器械产品注册和产品备案数据仅作为公众查询和网站公布的信息与相关系统不一致，请系统相关管理部门、注册人和生产企业医疗器械产品数据与监管部门备案数据的信息与医疗器械产品注册数据。

qixieyijao@mpa.gov.cn 【附件主题说明】“医疗器械数据问题”，附件正文请准确填写以下全部信息：1. 医疗器械注册证编号；2. 品牌（注册、变更、续展等）；3. 问题描述（500字以内）；4. 企业名称（全称）；5. 统一社会信用代码；6. 联系人姓名；7. 联系电话（手机和座机）；8. 联系邮箱；或致电国家药品监督管理局器械标准部电话010-88381951（此电话为低线值班电话非热线电话，并非上班时间企业业务咨询电话），更

REFINE | 10

医用隔离面罩测试报告

Test Report for face shield

检验报告 TEST REPORT

|        |                            |      |               |
|--------|----------------------------|------|---------------|
| 产品名称   | 防护面罩                       | 生产日期 | /年/月/日        |
| 商标     |                            | 委托单号 | 4011214       |
| 受检单位   | 深圳市东之星电子科技有限公司             | 检验类别 | 委托检验          |
| 委托单位   | 深圳市东之星电子科技有限公司             | 联系电话 | 0755-27806677 |
| 委托单位地址 | 深圳市宝安区沙井街道共和社区第一工业区A区26栋二楼 | 样品数量 | 10 副          |
| 委托生产单位 | 深圳市东之星电子科技有限公司             | 送样日期 | 2020-04-05    |
| 来样方式   | 送 样                        | 检验日期 | 2020-04-08    |
| 样品描述   | 眼护具类型：面罩 型号规格：EST02094     |      |               |
| 检验依据   | GB 14866-2006《个人用眼护具技术要求》  |      |               |
| 检验结论   | 检验项目符合上述检验依据要求。            |      |               |

主管： 审核： 主检： 马建

国标GB14866-2006

检验结果 TEST RESULTS

|      |           |
|------|-----------|
| 样品照片 | 图A 样品正面外观 |
| 样品照片 | 图B 样品侧面外观 |

主管： 审核： 主检： 马建

国标GB14866-2006

CPSIA Ca Prop65

Shenzhen General Standard Testing Services Co., Ltd.

Technical Report: RGS200326312

Date Received: Mar 26, 2020

Applicant: Shenzhen Eaststar Technology Co., Ltd.

Address: 2F, Building 26, Area A, First Industrial Zone, Gonghe, Shajing, Bao'an, Shenzhen

RESULT: COC

Sample Description: Face shield

TESTS

US - CPSIA & California "Proposition 65" Lead Requirements

US - CPSIA & California "Proposition 65" Phthalates Requirements

Issue date: Mar 31, 2020

Valid date: Mar 30, 2021

For and on behalf of General Standard Testing Services Co., Ltd.

美国CPSIA

GMT GUANGZHOU INSTITUTE OF MEASUREMENT AND TESTING TECHNOLOGY

TEST REPORTS

Information

Report No. YW20200299

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|                         |                                                                                                                     |
|-------------------------|---------------------------------------------------------------------------------------------------------------------|
| Report No.              | YW20200299                                                                                                          |
| Commission No.          | 4014359                                                                                                             |
| Testing Laboratory      | Guangzhou Institute of Measurement and Testing Technology                                                           |
| Address                 | No. 19, Jiantashan Road, Kexuecheng, Guangzhou, Guangdong, China                                                    |
| Applicant               | Shenzhen Eaststar Technology Co., Ltd.                                                                              |
| Address                 | 2F, Building 26, Area A, First Industrial Zone, Gonghe, Shajing, Bao'an, Shenzhen                                   |
| Information of samples  |                                                                                                                     |
| Product                 | FACE SHIELD                                                                                                         |
| Brand name              | /                                                                                                                   |
| Model No.               | EST02094                                                                                                            |
| Manufacturer            | Shenzhen Eaststar Technology Co., Ltd.                                                                              |
| Address                 | 2F, Building 26, Area A, First Industrial Zone, Gonghe, Shajing, Bao'an, Shenzhen                                   |
| Quantity submitted      | 12 pcs                                                                                                              |
| Date                    |                                                                                                                     |
| Date of receipt         | 2020-04-08                                                                                                          |
| Period of testing       | 2020-04-08 to 2020-04-21                                                                                            |
| Date of issue           | 2020-04-22                                                                                                          |
| Environmental condition |                                                                                                                     |
| Temperature             | 20.8 °C                                                                                                             |
| Relative humidity       | 59 %                                                                                                                |
| Reference standard      | ANSI/ISEA Z87.1-2015                                                                                                |
| Results                 | Please refer to the following pages.                                                                                |
| Conclusion              | Based on the test results given in this report, the submitted samples meet the requirements of ANSI/ISEA Z87.1-2015 |

See next page

主管： 审核： 主检： 马建

美国ANSI Z87.1

intertek Total Quality Assured.

Test Report

Number: SHAH01203539

Date: 15 Apr, 2020

Applicant: SHENZHEN EASTSTAR TECHNOLOGY CO., LTD

2F, BUILDING 26, AREA A, FIRST INDUSTRIAL ZONE, GONGHE, SHAJING, BAO, AN, SHENZHEN

Attn: LEO

Sample Description:

One (1) style of submitted sample said to be:

Item Name: FACE SHIELD

Item No.: EST02094

Country Of Origin: CHINA

Tests Conducted:

As requested by the applicant, for details refer to attached page(s).

Conclusion:

Tested samples: EN 166:2001 - Personal eye-protection - Specifications

Submitted samples: Excluding:

- Clause 8.2 - Materials

- Clause 7.1.2.3 - Diffusion of light

- Clause 7.1.4.2.2 - Complete eye-protectors and frames

- Clause 7.1.5.2 - Resistance to ultraviolet radiation (oculars only)

- Clause 9 - Marking

- Clause 10 - Information supplied by the manufacturer

Result: Pass

To be continued

Authorized By: Intertek Testing Services Ltd, Shanghai, Wenzhou Branch

Peter Chen General Manager

Intertek Testing Services Ltd, Shanghai Wenzhou Branch

Room 8205, 4F, No. 827, Wenzhou Avenue, Longmen District, Wenzhou City, Zhejiang Province, China 325000

Tel: +86 577 8555 8055 Fax: +86 577 8681 2119

www.intertek.com.cn

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欧盟EN166: 2001

intertek Total Quality Assured.

Test Report

Number: SHAH01203539

Date: 15 Apr, 2020

Applicant: SHENZHEN EASTSTAR TECHNOLOGY CO., LTD

2F, BUILDING 26, AREA A, FIRST INDUSTRIAL ZONE, GONGHE, SHAJING, BAO, AN, SHENZHEN

Attn: LEO

Sample Description:

One (1) style of submitted sample said to be:

Item Name: FACE SHIELD

Item No.: EST02094

Country Of Origin: CHINA

Tests Conducted:

As requested by the applicant, for details refer to attached page(s).

Conclusion:

Tested samples: EN 166:2001 - Personal eye-protection - Specifications

Submitted samples: Excluding:

- Clause 8.2 - Materials

- Clause 7.1.2.3 - Diffusion of light

- Clause 7.1.4.2.2 - Complete eye-protectors and frames

- Clause 7.1.5.2 - Resistance to ultraviolet radiation (oculars only)

- Clause 9 - Marking

- Clause 10 - Information supplied by the manufacturer

Result: Pass

To be continued

Authorized By: Intertek Testing Services Ltd, Shanghai, Wenzhou Branch

Peter Chen General Manager

Intertek Testing Services Ltd, Shanghai Wenzhou Branch

Room 8205, 4F, No. 827, Wenzhou Avenue, Longmen District, Wenzhou City, Zhejiang Province, China 325000

Tel: +86 577 8555 8055 Fax: +86 577 8681 2119

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欧盟EN166: 2001

CERTIFICATE OF CONFORMITY

Certificate No. ACIC20200428038KGH

Applicant: Shenzhen Eaststar Technology Co., Ltd

Address: 2F, Building 26, Area A, First Industrial Zone, Gonghe, Shajing, Bao'an, Shenzhen China

Manufacturer: Shenzhen Eaststar Technology Co., Ltd

Address: 2F, Building 26, Area A, First Industrial Zone, Gonghe, Shajing, Bao'an, Shenzhen China

Product: FACE SHIELD/Safety Goggles/Spectacles

Model(s): EST02094/EST02095/EST02096/EST02097

There are valid in connection with the standards:

EN166:2001

The EUT described above has been tested by us with the listed standards and found in compliance with the council PPE Directive EU 2016/425. It is possible to use CE marking to demonstrate the compliance with this PPE Directive.

CE

Authorized Signer: [Signature]

Date: [Date]

Shenzhen A Commitment Inspection & Certificate Co., LTD

No. 164-165, Pengda Road, Longgang Street, Longgang District, Shenzhen, China

Web: www.acic-china.com Email: acic@acic-china.com

CE-COC

Producer: Shenzhen Eastern Star Factory

QMS: ISO9001 and ISO14001 Audit Date: 10/09/2019

Auditee: Shenzhen Eastern Star Factory

Audit Date From: 10/09/2019

Audit Date To: 10/09/2019

Expiry Date of the Audit: Please refer to the producer profile in the amfori BSCI platform

Auditing Company: ALGI

Auditor's Name(s): Jouce Liang (Lead)

Auditing Branch (if applicable): ALGI China

amfori BSCI Trade with purpose

This is an extract of the on line Audit Report. The complete report is available in the amfori BSCI Platform. Access: www.bsciplatform.org for certified users only.

Amfori BSCI

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BCSCI

The Certificate of Quality Management System

Certificate No: 51820Q05058R05

Shenzhen Eaststar Technology Co., Ltd.

(Unified Credit Record: 91440300MASG03YQ8B)

Registration Address: 2/F, Building 26, Area A, The First Industrial Zone, Gonghe Community Shajing Street Office, Bao'an District, Shenzhen, Guangdong, China

Has been awarded this certificate for compliance with the standard

GB/T19001-2016 / ISO9001:2015

Production/Business Address: 2/F, Building 26, Area A, Zone, Gonghe Community 1st Industrial Zone, Shajing Street Office, Bao'an District, Shenzhen, Guangdong, China

Range of Products and Process: Production and sales of electronic plastic toys (glow stick, necklace, glow ball) (export only); Sales of glasses and daily necessities

Issued date: 2020-06-24 Valid until: 2023-06-23

Initial issued date: \*\*\*\*\* Renewal date: \*\*\*\*\*

This certificate is used with the requirements of valid laws and regulations which the certification scope involved. These requirements include but are not limited to administrative permits, scopes of qualifications, and CCC requirements etc.

Surveillance conformity label should be pasted below for continual effectiveness of this certificate.

The first Surveillance The second Surveillance

IAF CNAS

GM

Shenzhen Zhongbiao International Testing and Certification Co., Ltd.

Company address: 1151 (Zhongyuan Building), Xinghai Ming Cheng Community, Minzhen Street, Minzhen District, Shenzhen

Tel: 0755-82830999 Fax: 0755-82830999

Information of this certificate can be found on the official website of certification center (www.sgcc.com.cn) and CNCA official website (www.cnca.gov.cn)

ISO9001

# Test Report for safety goggle





## 深圳市东之星电子科技有限公司

第一类医疗器械生产备案凭证编号：粤深食药监械生产备20200059号

第一类医疗器械备案编号：粤深械备20200270（隔离面罩） 粤深械备20200286（护目镜）

备案人/生产企业/售后服务单位：深圳市东之星电子科技有限公司

生产地址：深圳市宝安区沙井街道共和社区第一工业区A区26栋二层

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