医 用 调 节 款 防 护 隔 离 面 罩 清 关 文 件

2020 年 **4** 月 **1** 日起海关严格检查文件

一.出口文件：

1.营业执照（经营范围有相关经营内容)

2.第一类医疗器械生产备案

3.第一类医疗器械备案

4.国标产品检验报告 GB14866-2006

二. 进口文件：

5.FDA（美国）

6.Z87.1 PPE 检测报告（美国）

7.CPSIA 检测报告（美国通用产品检测报告）

8.CA65 检测报告（美国加州通用产品检测报告）

9.BSCI 第三方验厂报告（欧美通用）

10.ISO9001 质量体系认证

11. CE 认证及检测报告 （欧盟 NB 机构本土检测）

12. CE/COC/PPE/2016-425（中介个人防护符合性声明）

13. CE/DOC/MDD/93-42-EEC（工厂医疗器械自我声明）

14. CE/DOC/PPE/2016-425 (工厂个人防护自我声明)

15.EN166 检测报告（欧盟）

三．出口通关其他资料：

16. 医疗器械产品出口销售证明（有需要提供）

17.合格证+说明书（随产品）

18.样品和包装图片

19.产品质量安全承诺书

20.出口医疗物资声明

21.厂名/产品批次/货号（合格证与外箱标明）

22.执行标准（外箱与合格证标明）

23.产品检验报告（工厂生产提供自检）

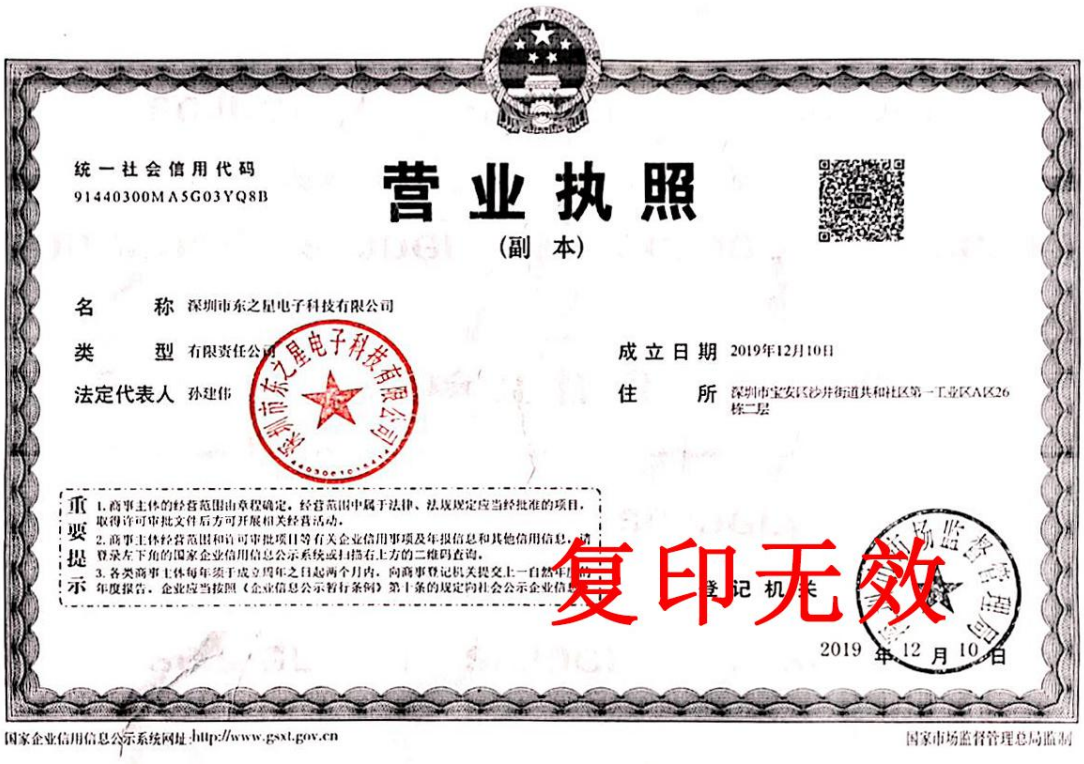
24.品牌授权书（有需要提供）

25.对外贸易经营备案

26.海关出口货物报关单

27.通关无纸化出口放行通知书

1.营业执照（验证方法：官网验证，国家工商局官网 www.saic.gov.cn 或天眼查官网 www.tianyancha.com ）



注释：医疗物资出口必备

2.第一类医疗器械生产备案（验证方法：官网验证，深圳市质监局官网 http://amr.sz.gov.cn/ ，仅 IE11 以上和 360 浏览器按标准步骤方可查阅，若无法登陆深圳市质监局官网查验，请电话沟通查验方法索取登录链接）

第一类医疗器械生产备案凭证

备案号：粤深食药监械生产备 20200059 号

企业名称	深圳市东之星电子科技有限公司			
住　　所	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			
生产场所	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			
法定代表人	孙建伟	企业负责人	孙建伟	
生产范围	14-14 医护人员防护用品			
生产产品列表	产品名称	产品备案号	登载日期	备注
	医用隔离面罩	粤深械备 20200270 号	20200403	/
	医用隔离眼罩	粤深械备 20200286 号	20200409	/
	/			

复印无效

备案部门（公章）

备案日期：2020-04-11

深圳市场局网站，可验证本证书，
方法 1：详见市场局网站“药械信息查询栏目”：
https://amr.sz.gov.cn/szyj/zwgk/search.jsp
方法 2：访问深圳市场局网站 http://amr.sz.gov.cn
点击首页的 -政务服务 -信息查询 -药械信息查询，内有一类备案等市局证书的查询界面。
以上网页，推荐 IE11 浏览器打开，并打开兼容视图设置，添加网址 sz.gov.cn。

注释：医疗物资出口必备

3.第一类医疗器械备案（验证方法：官网验证，深圳市质监局官网 http://amr.sz.gov.cn/ ，仅 IE11 以上和 360 浏览器按标准步骤方可查阅，若无法登陆深圳市质监局官网查验，请电话沟通查验方法索取登录链接）

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	91440300MA5G03YQ8B
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，EST02104
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 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，EST02104

注释：医疗物资出口必备

4. 国标产品检验报告 GB14866-2006(验证方法：电话查询020-32086293)

广东省质量监督眼镜检验站
GUANGDONG INSPECTION & TESTING LABORATORY FOR OPHTHALMIC OPTICS PRODUCTS
广州市眼镜质量监督检验站
GUANGZHOU INSPECTION & TESING LABORATORY FOR OPHTHALMIC OPTICS PRODUCTS

CNAS 中国认可 国际互认 检测 TESTING CNAS L1071

检 验 报 告
TEST REPORT

No. YW20200101　　第 1 页 / 共 5 页

产品名称 Product	防护面罩	生产日期 Manufactured Date	/年/月/日
商　标 Trade Mark	/	委托单号 Unique Number	4011214
受检单位 Inspected Entity	深圳市东之星电子科技有限公司	检验类别 Type of Test	委托检验
委托单位 Applicant	深圳市东之星电子科技有限公司	联系电话 Telephone	0755-27806677
委托单位地址 Applicant Add.	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	样品数量 Sampling Quantity	10　副
标称生产单位 Manufacture	深圳市东之星电子科技有限公司	送样日期 Application Date	2020-04-05
来样方式 Sampling Method	送　样	检讫日期 Complete Date	2020-04-08
样品描述 Sample Description	眼[illegible]类型：面罩　型号规格：EST020[illegible]		
检验依据 Ref. Documents	GB 14866-2006《个人用眼护具技术要求》		
检验结论 Test Conclusion	检验项目符合上述检验依据要求。 检验检测专用章 Issued by (Stamp) 签发日期：2020-04-09 Date of Issue		

复印无效

备注：
1. 样品特性及状态：正 常；
2. 检验环境条件：19.6 ℃，63 %RH；
3. 检验项目：结构、头箍、镜片规格、镜片外观质量、屈光度、棱镜度、可见光透射比、耐热性能、耐腐蚀性能；
4. 委托方要求不检项目：抗冲击性能、有机镜片表面耐磨性能、标志。

主管：李育豪　审核：张洁　主检：马骥

地址：广州市科学城尖塔山路19号　邮政编码：510663
电话/传真：020-32086293　电子邮箱：glass320862930126.com

ADD：No.19 Jiantashan Road,Guangzhou Science City,Guangzhou,P.R.China
P.C.：510663　TEL/FAX：020-32086293　E-MAIL：glass320862930126.com

注释：医疗物资出口必备

5.FDA（美国）（验证方法： 官网验证， 打开 FDA 网址链接 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm，输入注册号 10068326，点击搜索）

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

SHENZHEN EASTSTAR TECHNOLOGY CO., LTD
2F,BUILDING 26, AREA A,FIRST INDUSTRIAL ZONE,
GONGHE, SHAJING, BAO'AN, SHENZHEN, GUANGDONG
518125, CHINA has completed the FDA Establishment Registration (as foreign exporter, contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: Joseph Iacona

Telephone: +1 586-8730503 / E-mail: sales@canovelty.com

Owner/Operator Number: 10068326
Registration Number: 3016777545
Device Listing#:

Listing No	Code	Device Name
D388175	KPY	Shield, protective, personnel (FACE SHIELD)
D388555	IWS	Shield, eye, radiological (Safety Goggles)

Pursuant to 21 CFR Part 807, Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and may constitute misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. This certification only serves as an proof upon FDA medical device establishment registration. Interested parties may check the registration information on FDA Establishment Registration & Device Listing database using the Owner/Operator Number. Due to the operation schedule of FDA, checking of information maybe failed. Please wait after the next Monday on which FDA updates their database.

Executive Director
Issued: July 24, 2020
Expiration Date: Dec. 31 2020

注释：医疗器械个人防护美国进口必备

6.Z87.1 PPE 检测报告（美国）

GIMT GUANGZHOU INSTITUTE OF MEASUREMENT AND TESTING TECHNOLOGY

TEST REPORTS

Information

Report No.YW20200299 Page 1 of 4

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.	EST02103
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 ℃
Relative humidity	59 %
Reference standard	ANSI/ISEA Z87.1-2015 American National Standard for Occupational and Educational Personal Eye and Face Protection Devices
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

复印无效

——See next page——

主管：李育豪 李育豪 审核：张洁 张洁 主检：李一洲 李一洲

广州计量检测技术研究院 检验检测专用章

7.CPSIA 检测报告（美国通用产品检测报告，不含加州）（验证方法：邮件查询，info@gstlab.com）

GST®

Test Report

Report No.: RGST200326312 Date: Mar 30, 2020 Page 1 of 6

Applicant : Shenzhen Eaststar Technology Co.,Ltd

Address : 2F,Building26, AreaA, First Industrial Zone, Gonghe ,Shajing, Bao an, Shenzhen

Report on the submitted sample(s) said to be:

Sample(s) Name : Face shield

Sample(s) received date : Mar 26, 2020

Testing period : From Mar 26, 2020 to Mar 30, 2020

Test Request	Conclusion
(1) As specified by client, to determine the Lead content in the submitted sample(s) in accordance with California "Proposition 65".	Pass
(2) As specified by client, to determine the Lead content in the submitted sample(s) in accordance with Consumer Product Safety Improvement Act of 2008(H.R. 4040) & H.R.2715 amendment Title 1 section 101- Children's products containing lead; lead paint rule.	Pass
(3) As specified by client, to determine the DEHP、DBP、BBP、DINP、DIBP、DPENP、DHEXP and DCHP content in the submitted sample(s) in accordance with Consumer Product Safety Improvement Act of 2008(H.R. 4040) & H.R.2715 amendment &16 CFR Part 1307-Prohibition of Children Toys and Child Care Articles Containing Specified Phthalates, to determine the DIDP content in the submitted sample(s) in accordance with California "Proposition 65".	Pass

****

Approved by

Ben Miao

Technical Manager

Shenzhen General Standard Testing Services Co.,Ltd
2/F&3/F-5/F East Wing,Building C10,Zhu'ao 2nd industrial zone,Xixiang Street,Bao'an District, Shenzhen, Guangdong, China
Tel: 86-0755-36307999 Website: www.gst-lab.com

注释：美国通用产品进口必备

8.CA65 检测报告（美国加州）（验证方法：邮件查询，info@gstlab.com）

Shenzhen General Standard Testing Services Co.,Ltd
2/F&3/F-5/F East Wing, Building C10,Zhu'ao 2nd industrial zone,
Xixiang Street, Bao'an District, Shenzhen, Guangdong, China
Tel: 86-0755-36307999 Website: www.gst-lab.com

CERTIFICATE OF CONFORMITY

Technical Report: RGST200326312

Date Received: Mar 26, 2020
Applicant: Shenzhen Eaststar Technology Co.,Ltd
Address: 2F,Building26, AreaA ,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

Ben Miao, Technical Manager
For and on behalf of General Standard Testing Services Co., LTD

注释：美国加州通用产品进口必备

9.BSCI（第三方验厂，欧美通用）验证方法：官网验证，https://www.bsciplatform.org/home）

Producer : Shenzhen Eastern Star Factory

DBID : 369297 and Audit Id : 162178 Audit Date : 10/09/2019

Audit Type : Follow-up Audit

amfori BSCI Trade with purpose

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) :	Joucel Jiang(Lead)
Auditing Branch (if applicable) :	ALGI China

复印无效

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 entitled users only.

注释：社会责任体系验厂认证，大买家采购必备

10. ISO9001　质量体系认证验证方法:官网验证,www.szccac.com）

ISO 9001

The Certificate of
Quality Management System

Certificate No: 51820Q05058R0S

Shenzhen Eaststar Technology Co., Ltd.

(Unified Credit Record: 91440300MA5G03YQ8B)

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, 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.

Suveillance conformity label should be pasted below for confinual effectiveness of this certificate.

The first Surveillance

The second Surveillance

复印无效

MANAGEMENT SYSTEM
CNAS C172-M

GM

Shenzhen Zhongbiao International Testing and Certification Co., Ltd.

Company address: 1103（Zhenye Building), Xing Hai Ming Cheng VII, Intersection of Qian Hai Road & Shen Nan Road,Xing Hai Ming Cheng Community, Nantou Street, Nanshan District, Shenzhen

TEL：0755-82833099　　FAX：0755-82839499

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

注释：社会责任体系验厂认证，大买家采购必备

11. CE 认证 （欧盟 NB 机构本土检测）验证方法：邮件验证，bernhard.schmitz@ecs-eyesafe.de）

ECS GmbH - European Certification Service

CE

EU type-examination certificate

C2980.1EASTSTAR

Applicant / manufacturer	Shenzhen Eaststar Technology Co., Ltd 2F, Building 26, Area A First Industrial Zone Gonghe, Shajing Baoan SHENZHEN P.R.CHINA
Identification of the manufacturer	EASTSTAR
Product type	Face shield
Model names	EST02103
Standard(s) / technical rules	Essential requirements according to Annex II of the PPE-Regulation (EU) 2016/425 EN 166 : 2001 (partially applied)
Test report(s)	1117-ECS-20 / MR 11171-ECS-20
Materials, optical and mechanical properties	Polycarbonate, foam, elastic headband Luminous transmittance NA 89% No protection against any mechanical impact Protection against splashes of liquids (3)
Marking	EASTSTAR 1 3 CE

Herewith, ECS certifies that the named model complies with the essential requirements for health and safety as they are provided by the European Regulation (EU) 2016/425 for Personal Protective Equipment. This certificate is based both / either on the test results as they are summarized in the named test reports and/or on the technical documentation as it is delivered by the manufacturer. The applicant / manufacturer agrees to the General Business Rules of the ECS GmbH and to additional agreements as they are named in the application for conformity assessment.
The eye-protection device is to be marked as assigned. Either / both the frame and/or the ocular, spectacle, goggle or shield must be signed, as appropriate. If different markings have been assessed, the lowest marking must be applied, respectively.
The validity of this EU type-examination certificate will expire on the date as mentioned below, and/or if the manufacturer modifies the safety-relevant properties of this product with comparison to the tested one and/or if the requirements in the standards or technical rules will be revised and/or tightened.
Name, address and identification number 1883 of the notified body ECS are to be indicated in the information brochure of this product.

This EU type-examination certificate is valid until 2021-04.

ECS GmbH
Notified Body 1883
09/05/20

Dr. Bernhard Schmitz
ECS-Certification

European Certification Service ECS GmbH Aalen

ECS GmbH – European Certification Service
Augenschutz und Persönliche Schutzausrüstung
Laserschutz und Optische Messtechnik
Hüttfeldstraße 50
73430 Aalen, Germany

注释：欧盟进口必备

12. CE/COC/PPE/2016-425（中介符合性声明）（验证方法：官网查询，http://www.acic-china.com）

Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

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/EST02103/EST02104*

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复印无效

Authorized Signer :

Date :

This certificate of conformity ACIC is based on a single evaluation of the submitted sample(s) of the above mentioned product. It does not imply an assessment of the whole production and other relevant directives have to be observed.

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

13. CE/DOC/MDD/93-42-EEC（工厂自我声明）（验证方法：邮件查询， info@aaglow.com）

Shenzhen Eaststar Technology Co., Ltd

2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Baoan, Shenzhen

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: Shenzhen Eaststar Technology Co., Ltd 2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Bao。an, Shenzhen

We declare under our sole responsibility that

the medical device: Disposable Face Shield

UMDNS code: 11961,shields,face

Size: 33 X 22cm; 28 X 19cm; 19 X 70cm

Intended use:

Protective wear to act from transmissible virus!

of class: / I

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.The declaration is valid in connection with the"final inspection report" of the device

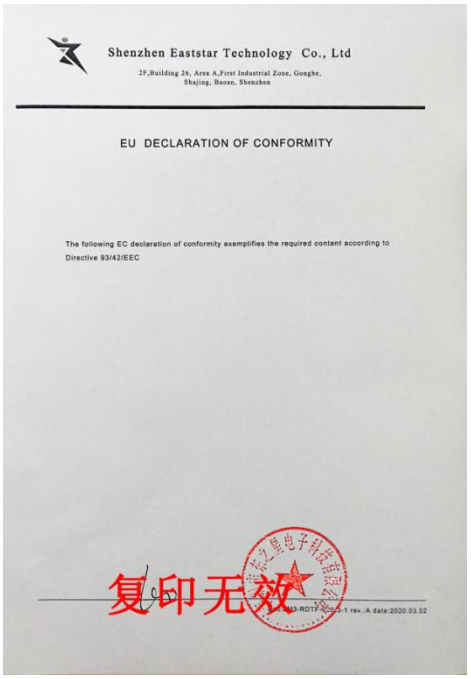
Conformity assessment procedure:/ Directive 93/42/EEC Annex II,excluding Section 4

EC REP: MT Promedt Consulting Gmbh Altenhofstrasse 80,66388 St.Ingbert Germany

Guangzhou 2020.03.02 Sunjianwei General Manager

Place,date/ Name and function

复印无效



Shenzhen Eaststar Technology Co., Ltd

2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Baoan, Shenzhen

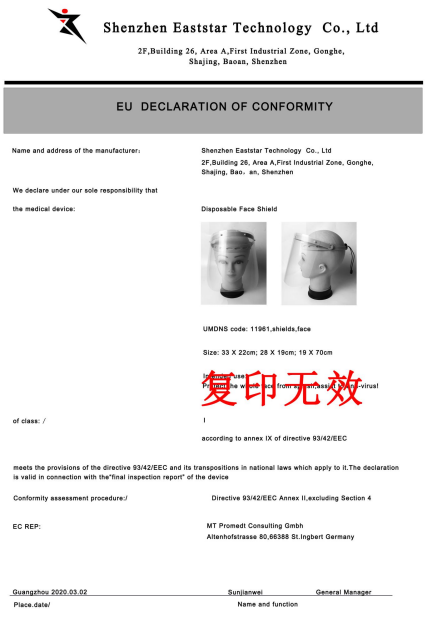
EU DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC

复印无效

Doc:LM3-RDTF-2020.3-1 rev.:A date:2020.03.02

14. CE/DOC/PPE/2016-425（工厂自我声明）（验证方法：邮件查询， info@aaglow.com）



Shenzhen Eaststar Technology Co., Ltd

2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Baoan, Shenzhen

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: Shenzhen Eaststar Technology Co., Ltd 2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Bao。an, Shenzhen

We declare under our sole responsibility that

the medical device: Disposable Face Shield

UMDNS code: 11961,shields,face

Size: 33 X 22cm; 28 X 19cm; 19 X 70cm

Intended use:

Protective wear to act from transmissible virus!

of class: / I

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.The declaration is valid in connection with the"final inspection report" of the device

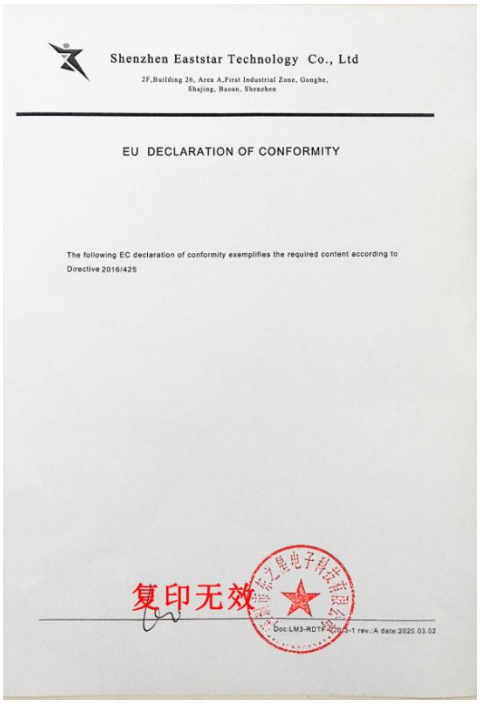
Conformity assessment procedure:/ Directive 93/42/EEC Annex II,excluding Section 4

EC REP: MT Promedt Consulting Gmbh Altenhofstrasse 80,66388 St.Ingbert Germany

Guangzhou 2020.03.02 Sunjianwei General Manager

Place,date/ Name and function

复印无效



Shenzhen Eaststar Technology Co., Ltd

2F,Building 26, Area A,First Industrial Zone, Gonghe, Shajing, Baoan, Shenzhen

EU DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 2016/425

复印无效

Doc:LM3-RDTF-2020.3-1 rev.:A date:2020.03.02

15. EN166-2001 检测报告（欧盟）（验证方法：邮件查询，service.china@intertek.com）

intertek
Total Quality. Assured.

Test Report Number: SHAH01203539

Applicant: SHENZHEN EASTSTAR TECHNOLOGY CO., LTD
2F,BUILDING 26, AREA A,FIRST INDUSTRIAL ZONE, GONGHE, SHAJING, BAO，AN, SHENZHEN
Attn: LEO

Date: 15 Apr, 2020

Sample Description:
One(1) style of submitted sample said to be :
Item Name : FACE SHIELD.
Item No. : EST02103.
Country Of Origin : CHINA.

****

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

****

Conclusion:

Tested samples	Standard	Result
Submitted samples	EN 166:2001 – Personal eye-protection — Specifications Excluding: - Clause 6.2 – 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	Pass

****

To be continued

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

Peter Chen
General Manager

Intertek Testing Services Ltd., Shanghai Wenzhou Branch 上海天祥质量技术服务有限公司温州分公司 检验检测专用章

Intertek Testing Services Ltd., Shanghai Wenzhou Branch
上海天祥质量技术服务有限公司温州分公司

Room 8205, 4F, No.827, Wenzhou Avenue, Longwan District, Wenzhou City, Zhejiang Province, China. 325000
中国浙江省温州市龙湾区温州大道 827 号(源大创业学院)4 楼 8205 室 325000

Tel: +86 577 8555 6055
Fax: +86 577 8881 2119
www.intertek.com
www.intertek.com.cn

16.医疗器械产品出口销售证明

医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号
Certificate No.：粤深市监械出 2020Y087

产品名称：1、医用隔离面罩 2、医用隔离眼罩
Product(s)：1、Medical Isolation face shield 2、Medical isolation eye mask

规格型号：1、EST02094 2、EST02095 3、EST02103 4、EST02104
Model：1、EST02094 2、EST02095 3、EST02103 4、EST02104

产品注册或备案凭证号
Registration certificate(s)：1、粤深械备 20200270 号 2、粤深械备 20200286 号

生产企业：深圳市东之星电子科技有限公司
Manufacturer: Shenzhen Eaststar Technology CO.,Ltd

生产企业住所：广东省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
Address of manufacturer: 2F,Building26,Area A,First Industrial Zone,Gonghe, Shajing,Bao'an,Shenzhen

生产许可或备案凭证号
Manufacturing License(s)：粤深食药监械生产备 20200059 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

深圳市市场监督管理局
Market Supervision Administration of Shenzhen Municipality

2020 年/ Year 5 月/Month 25 日/Day.

（此证明有效期与产品备案凭证效期相同，且最长不超过两年）
（This certificate is valid for a period equal to the life of the product registration certificate and up to two years at a maximum）

注释：外贸出口销售必备

17. 合格证+说明书（随产品）

ANDX

Certificate of Conformity

品名：防护面罩

Product name: FACE SHIELD Models: EST02103

Product material: PET + Sponge + Nylon Ribbon

Lot number: 08002 Quality Grade:

QC PASS 检01

Implementation Standard: GB14866-2006 IQC: QC01

Period of validity: Two years Production date: April 2020

工厂：深圳市东之星电子科技有限公司

Factory: Shenzhen Eaststar Technology Co., Ltd

厂址：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

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

TEL: +86-755-27806677 EMAIL: info@aaglow.com

MADE IN CHINA

Instructions

1. Open the package

2. Tear off the protective film

3. Wear it on the head

4. This product is disposable Please dispose properly after use.

[Product name] double sided anti-fog protective mask (non-sterile)

[Structure and composition] face shield :double-sided anti-fog, Environmental protection and ultra transparent PET; sponge: environmental Protection and breathable sponge elastic nylon webbing.Wipe paper (Optional)

[Prevention and control level] 10 level protective mask

[Executive standard] GB14866-2006

[Product character] local protection for face, primary protection, anti-fog, Anti-spray, anti-splash.

[Application] disease control and prevention, dentistry, facial features, Equipment cleaning, catering and security, chemical workers facial Protection for industry personnel who need face protection,face and Eyes and nose protection.

[Storage method] the product should be stored in a dry, ventilated and Pollution-free area, and the temperature should be 0-40˚C,keep away From fire, dust and direct sunlight.

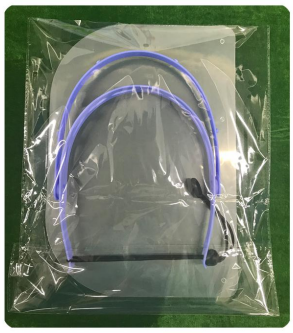
[Caution]

1. This product can't be used as anti-epidemic product alone. In the environment polluted by virus, please use it with mask,In order to effectively stop the spread of the virus.
2. This product is disposable product, repeat use is prohibited.
3. If this product is used for epidemic prevention, please handle it according to the management regulations of medical device waste after use, and do not discard it at will.

18. 产品样品图片以及外包装图片（1000/箱）

深圳市东之星电子科技有限公司

防护面罩产品包装图片



单支/袋

十支/大袋

正唛

正唛

19.产品质量安全承诺书

质量安全承诺书

兹确认，本次报关出口医疗物资信息如下：

产品名称	产品数量	注册证号	生产厂商
医用隔离面罩	2400 个	粤深械备 20200270 号	深圳市东之星电子科技有限公司

我公司承诺上述产品均已取得我国医疗器械产品注册证书，符合加拿大相关质量安全要求。我公司对以上内容承担如实申报之责任。

特此承诺。

深圳市东之星电子科技有限公司

2020 年 4 月 20 日

20. 出口医疗物资声明

出口医疗物资声明
Export Declaration of Medical Supplies

兹声明，本次报关出口医疗物资信息如下：

We hereby declare as follows the export information of medical supplies for this customs declaration:

产品名称 (含规格、型号) Product Name (including specifications and model)	产品 数量 Product Quantity	国外质量标准名称 The Name of Quality Standards of the Foreign Country	国外质量标准要求 Quality Requirements of the Foreign Country	进口国(地区) Importing Country/ Region	生产厂商 Producer
医用隔离面罩 Face shield EST02103 品牌：ANDX Brand: ANDX	72000个 72000pcs	ANSI Z87.1	FDA	美国 America	深圳市东之星电子科技有限公司 Shenzhen Eaststar Technology Co.,Ltd

上述产品取得 FDA 质量标准认证（注册），符合 美国 （地区）相关质量标准和安全要求。我公司对以上内容承担如实申报之责任。

The above products are certified or registered by FDA quality standards and compliant with relevant quality standards and safety requirements of America country/region. Our company is responsible for the truthful declaration of the above information.

特此声明。

公司名称（盖章）深圳市东之星电子科技有限公司

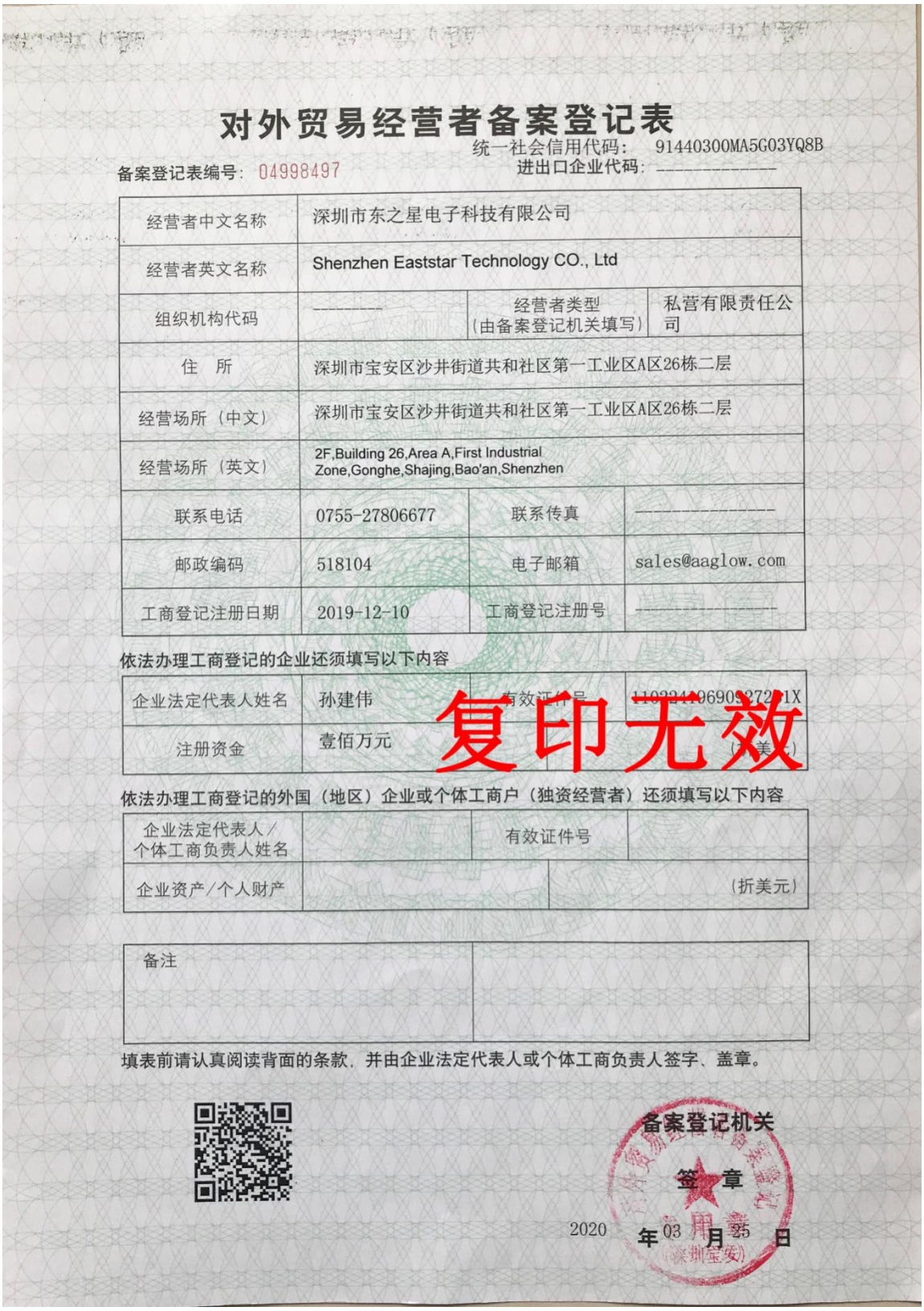
Company Name(Seal) **Shenzhen Eaststar Technology Co., Ltd**

2020 年 8 月 20 日

August 20, 2020

注释：医疗物资出口必备，海关必检

25. 对外贸易经营备案



对外贸易经营者备案登记表

统一社会信用代码：91440300MA5G03YQ8B

备案登记表编号：04998497　　进出口企业代码：----------

经营者中文名称	深圳市东之星电子科技有限公司		
经营者英文名称	Shenzhen Eaststar Technology 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	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		
经营场所（中文）	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		
经营场所（英文）	2F,Building 26,Area A,First Industrial Zone,Gonghe,Shajing,Bao'an,Shenzhen		
联系电话	0755-27806677	联系传真	----------
邮政编码	518104	电子邮箱	sales@aaglow.com
工商登记注册日期	2019-12-10	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	孙建伟	有效证件号	1[illegible]1X
注册资金	壹佰万元		（折美元）

复印无效

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／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

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负责人签字、盖章。

备案登记机关

签　章

2020 年 03 月 25 日

注释：出口必备

26. 海关出口货物报关单

中华人民共和国海关出口货物报关单

531720200170068080

预录入编号：531720200170068080　　海关编号：531720200170068080　　(深机场关)　　页码/页数：1/1

境内发货人 (91440300MA5G03YQ8B) 深圳市东之星电子科技有限公司	出境关别 (5317) 深机场关	出口日期	申报日期 20200420	备案号		
境外收货人 MA[illegible] [illegible]DS FACTORY	运输方式 (5) 航空运输	运输工具名称及航次号	提运单号 29736947[illegible]			
生产销售单位 (91440300MA5G03YQ8B) 深圳市东之星电子科技有限公司	监管方式 (0110) 一般贸易	征免性质 (101) 一般征税	许可证号			
合同协议号 MGF-009	贸易国(地区) (USA) 美国	运抵国(地区) (USA) 美国	指运港 (USA000) 美国	离境口岸 (471001) 深圳宝安国际机场		
包装种类 (22) 纸制或纤维板制盒/箱	件数 10	毛重(千克) 97	净重(千克) 83	成交方式 (3) FOB	运费	保费	杂费
随附单证及编号 随附单证2:代理报关委托协议（电子）;合同;装箱单;企业提供的声明;企业提供的其他;发票							
标记唛码及备注 备注:物流园区 医疗器械产品备案号：粤深械备20200270号 N/M							

项号	商品编号	商品名称及规格型号	数量及单位	单价/总价/币制	原产国(地区)	最终目的国(地区)	境内货源地	征免
1	3926909090	医用隔离面罩 1|2|用于医疗机构检查治疗时起防护作用|塑料制 |ANDX牌|EST02094型，33*22CM	83千克 2400个	[illegible]000 [illegible].00 美元	中国 (CHN)	美国 (USA)	(44031)深圳特区	照章征税 (1)

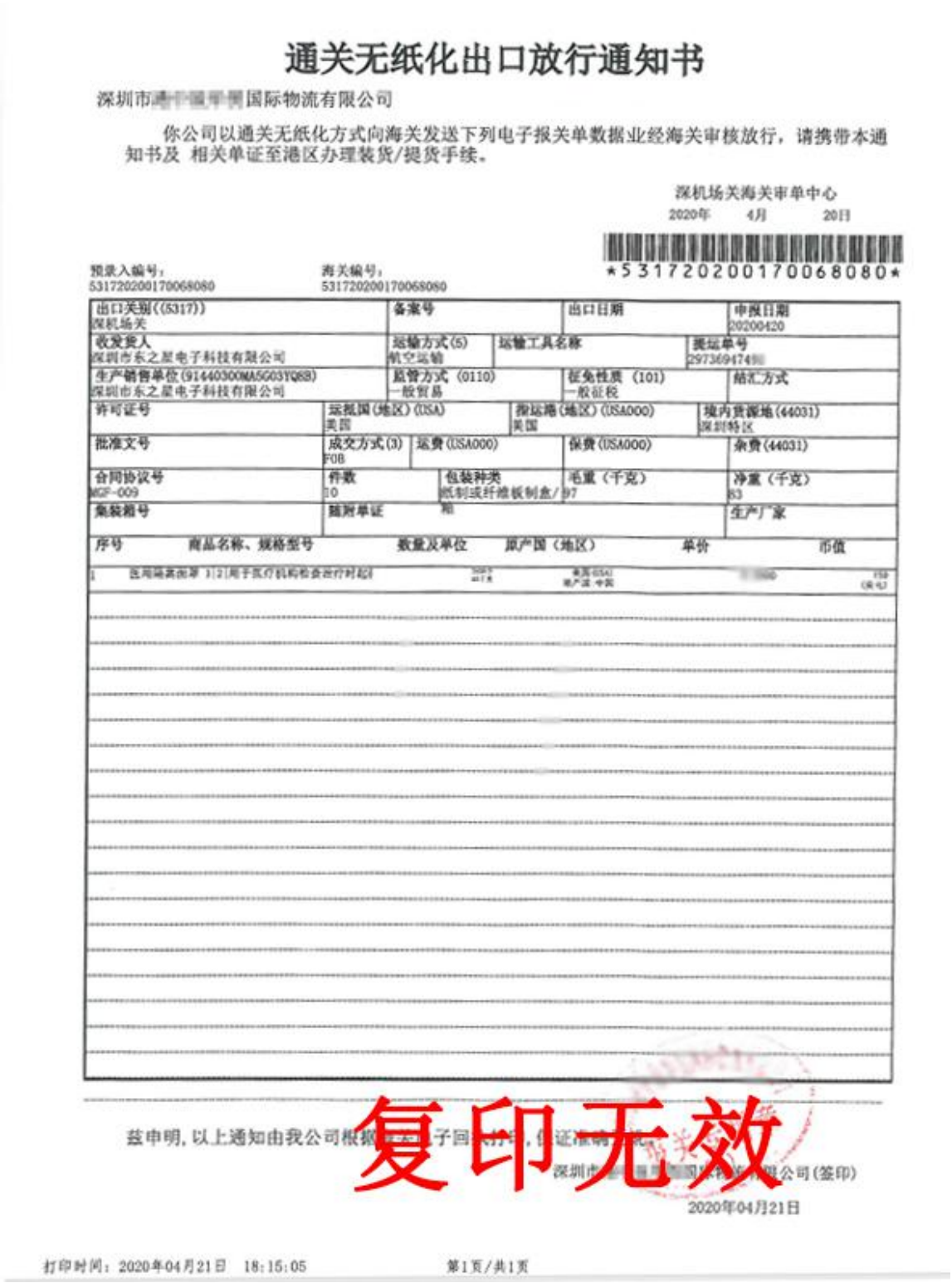
特殊关系确认:否　　价格影响确认:否　　[illegible]确认:否

报关人员　　报关人员证号53010144　　电话　　兹申明对以上内容承担如实[illegible]依法纳税之法律责任　　海关批注及签章

申报单位 (91440300192442494T)深圳市[illegible]际物流有限公司　　申报单位（签章）

注释：百分百通关，实际报关单证明

27. 通关无纸化出口放行通知书



通关无纸化出口放行通知书

深圳市[redacted]国际物流有限公司

你公司以通关无纸化方式向海关发送下列电子报关单数据业经海关审核放行，请携带本通知书及 相关单证至港区办理装货/提货手续。

深机场关海关审单中心

2020年 4月 20日

53172020017006808O

预录入编号：531720200170068080　　海关编号：531720200170068080

出口关别((5317)) 深机场关	备案号	出口日期	申报日期 20200420
收发货人 深圳市东之星电子科技有限公司	运输方式(5) 航空运输	运输工具名称	提运单号 297369474[redacted]
生产销售单位(91440300MA5GG3YQ8B) 深圳市东之星电子科技有限公司	监管方式 (0110) 一般贸易	征免性质 (101) 一般征税	结汇方式
许可证号	运抵国(地区)(USA) 美国	指运港(地区)(USA000) 美国	境内货源地(44031) 深圳特区
批准文号	成交方式(3) FOB	运费(USA000)	保费(USA000)	杂费(44031)
合同协议号 MGF-009	件数 10	包装种类 纸制或纤维板制盒/箱	毛重（千克） 97	净重（千克） 83
集装箱号	随附单证		生产厂家

序号	商品名称、规格型号	数量及单位	原产国（地区）	单价	币值
1	医用喷雾面罩 1|2|用于医疗机构检查治疗时起[redacted]	[redacted]	美国(USA) 最终目的国（地区）：中国	[redacted]	[redacted]

兹申明，以上通知由我公司根据[redacted]电子回[redacted]，保证[redacted]

深圳市[redacted]有限公司(签印)

2020年04月21日

复印无效

打印时间：2020年04月21日 18:15:05　　第1页/共1页

注释：百分百通关，实际放行通知书证明