



**Fiscal Year 2020
FDA REGISTRATION CERTIFICATE**

Certificate No.: JF-FDA-0323-0103

Certificate Holder:

**SHENZHEN 123 ENERGY CONSERVATION
ELECTRICAL TECHNOLOGY CO., LTD.**

101, Shuisheng Innovation Industrial Park, Tangwei Community, Fenghuang Street,
Guangming District, Shenzhen, Guangdong, 518107, CHINA

has completed the FDA Establishment Registration (as manufacturer , foreign
exporter, contract manufacturer) and Device Listing with the US Food & Drug
Administration.

Registration Number: N

Owner/Operator Number: 10063961

Device Listing:

Device#	Product Codes	Device Name
D377450	KHA	MASK, SCAVENGING (Disposable mask)

Registration Expiration Date: 2020-12-31

J&F TECHNOLOGY SERVICES LLC has verified and declares that the above stated facility is registered with the US Food & Drug Administration, Center for Drug Evaluation and Research, Office of Drug Registration and Listing pursuant to the Code of Federal Regulation 21 CFR 207, on the data state above, and makes no other representations and warranties, nor does this certificate makes other representations and warranties to other person or entity other than the name certificate holder, for whose sole benefit it is issued. J&F TECHNOLOGY SERVICES LLC assumes no liability to any person or entity in connection with the foregoing. J&F TECHNOLOGY SERVICES LLC is a private registration agent and is not affiliated with the US Food and Drug Administration.

J&F TECHNOLOGY SERVICES LLC.

2424 Morris Ave 818 Union

NEW JERSEY 07083

United States





Attestation of Conformity

No. ICR Polska/M3600542



**Name and address
of Registered Manufacturer:**

Shenzhen One Two Three Energy Saving Electrical
Technology Co., Ltd.
101, Shuisheng Technology Industrial Park, Tangwei
Community, Fenghuang Street, Guangming District,
Shenzhen

Product name:

3D Super Stereoscopic N95 Daily Protective Mask

Product type/model:

yes-sc-kz-01

Trade mark:

益而善

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive:

Medical Device Directive 93/42/EEC

**Conformity assessment
procedure:**

EC Declaration of Conformity (Annex VII of Directive
93/42/EEC)

Classification:

Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents:

EN 14683:2019

**Applied Quality
Management System**

n/a

This AoC will remain valid only if Quality Management System Certificate remains valid.

The assessment process has been carried out in accordance with the program PC-P-07-07.

Evaluation has been carried out in accordance with test report made by:

- Shenzhen One Two Three Energy Saving Electrical Technology Co., Ltd.
101, Shuisheng Technology Industrial Park, Tangwei Community, Fenghuang Street,
Guangming District, Shenzhen

No. of test report:

ESET200316007

Issue date:

19.03.2020

Expiration date:

18.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR
Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have
been evaluated and meet the requirements of the aforementioned standard.



Director: Rafal Kalinowski

Warsaw, 19. 03. 2020.

ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrqa.com





Certificate

ICR Polska/CE/V/ 00RA111

Name and address of certificate owner: Shenzhen One Two Three Energy Saving Electrical Technology Co., Ltd.
101, Shuisheng Technology Industrial Park, Tangwei Community,
Fenghuang Street, Guangming District, Shenzhen

Name and address of manufacturer: Shenzhen One Two Three Energy Saving Electrical Technology Co.,Ltd.
101, Shuisheng Technology Industrial Park, Tangwei Community,
Fenghuang Street, Guangming District, Shenzhen

Product name: Protective Mask

Product types: yes-sc-kz-01

Product trademark: 益而善™

- This certificate confirms that the product meets the requirements of the following standard
- The conformity was demonstrated based on following standard(s) listed by European Commission as harmonized with **Directive 93/42/EEC**.

EN 14683:2019

The certification has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report(s) No.: ESET200316007

Test conducted by: Shenzhen One Two Three Energy Saving Electrical Technology Co.,Ltd.

Certificate issue date: 02.04.2020

Expiration date: 01.04.2025

NOTES:

- This certificate refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample
- This certificate does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product
- This certificate holder shall use this certificate in connection to declaration of conformity and technical data relevant for the product the certificate was issued

Certificate modifications: -

Director: Rafal Kalinowski

Warsaw, 02.04.2020

ICR Polska Co. Ltd.
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03-944 Warsaw, POLAND
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统一社会信用代码
91440300567096760X

营业执照 (副本)



名称 深圳市一二三节能电器科技有限公司

类型 有限责任公司

法定代表人 李华明

成立日期 2011年01月10日

住所 深圳市光明区凤凰街道雅居社区水圣科技工业园1号101

市场监督管理

重要提示

1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左上方的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登记机关





第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 20205246 号

企业名称	深圳市一二三节能电器科技有限公司
法定代表人	李华明
企业负责人	李华明
经营方式	批零兼营
住 所	深圳市光明区凤凰街道塘尾社区水圣科技工业园 1 号 101
经营场所	深圳市光明区凤凰街道塘尾社区水圣科技工业园 1 号 101
库房地址	深圳市光明区凤凰街道塘尾社区水圣科技工业园 1 号 101
经营范围	2002 年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（体外诊断试剂除外），6840（诊断试剂需低温冷藏运输贮存），6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 2017 年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，6840 体外诊断试剂，6840 体外诊断试剂（不需低温冷藏运输贮存），以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外

备案部门（公章）

备案日期：2020 年 02 月 27 日





商事登记簿查询(商事主体登记及备案信息查询)

深圳市一二三节能电器科技有限公司 2020年03月24日 的变更信息

打印

变更前一般经营项目	节能电器、净水器、过滤器装置、饮水机、开水机、空气净化器、洗碗机前、家用小电器的技术开发与销售；电器领域的技术开发、技术咨询、技术服务；软件开发；国内贸易、货物及技术进出口。(法律、行政法规、国务院决定规定在登记前须经批准的项目除外)
变更后一般经营项目	节能电器、净水器、过滤器装置、饮水机、开水机、空气净化器、洗碗机前、家用小电器的技术开发与销售；电器领域的技术开发、技术咨询、技术服务；软件开发；产品的开发与销售；国内贸易、货物及技术进出口。(法律、行政法规、国务院决定规定在登记前须经批准的项目除外)
变更前章程修正案通过日期	2020-03-07
变更后章程修正案通过日期	2020-03-20
变更前许可信息	《建设项目环境影响评价批复》0、《建设项目环境影响评价批复》(深光环批(2015)1260122号)、《医疗器械生产企业许可证》；《医疗器械经营企业许可证》0
变更后许可信息	《建设项目环境影响评价批复》0、《医疗器械经营企业许可证》0、《建设项目环境影响评价批复》(深光环批(2015)1260122号)、《医疗器械生产企业许可证》；《医疗器械经营企业许可证》0、《医疗器械生产企业许可证》；《医疗器械经营企业许可证》0
变更前许可经营范围	节能电器、净水器、过滤器装置、饮水机、开水机、空气净化器、洗碗机前、家用小电器的生产；电子产品、电器零部件的研发、生产、加工及销售；第二类医疗器械(医用口罩)、日用口罩(非医用)、劳动防护用品、日用品的生产及销售；计算机及配件、电子元件、通讯器材、塑胶零件、皮具零件的研发、销售、维修；
变更后许可经营范围	节能电器、净水器、过滤器装置、饮水机、开水机、空气净化器、洗碗机前、家用小电器的生产及销售；电子产品、电器零部件的研发、生产、加工及销售；第一类医疗器械、第二类医疗器械、第三类医疗器械、消毒产品的技术开发、生产及销售；日用品的生产及销售；计算机及配件、电子元件、通讯器材、塑胶零件、皮具零件的研发、销售、维修；









Model Number: KN95

Size of mask: 15.5*10.5cm

Expiration date: 2 years

Estimated packing:

Carton size: 67*42.5*31.5cm, 2000pcs/ CTN,

10pcs/ bag, 5 bags/ box, 50pcs/ box

Gross weight: 8.5kgs/ CTN