Large disposable mask manufacturer

ISO9001

KN95

PROTECTIVE MASK

GB2626—2006

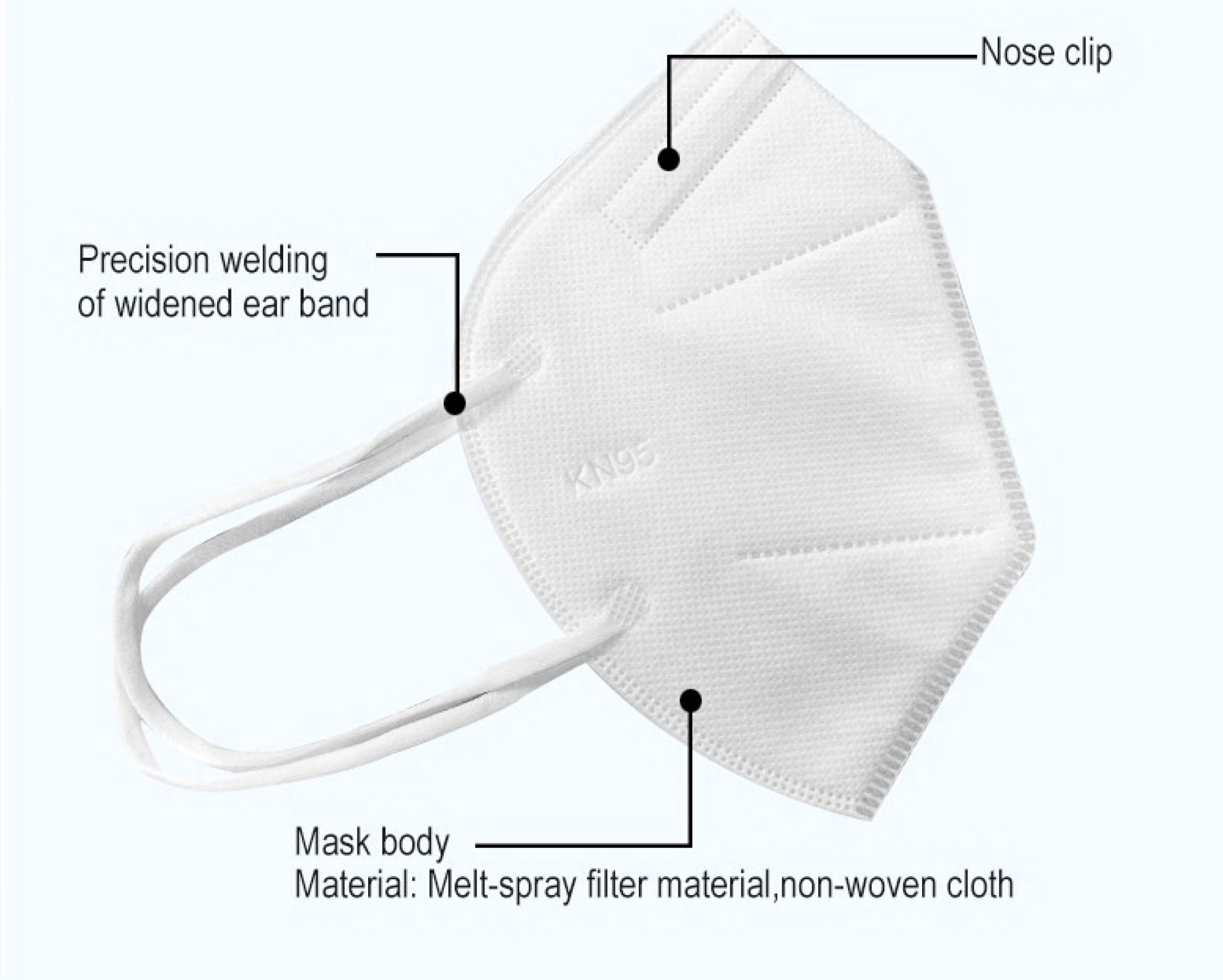
One time use

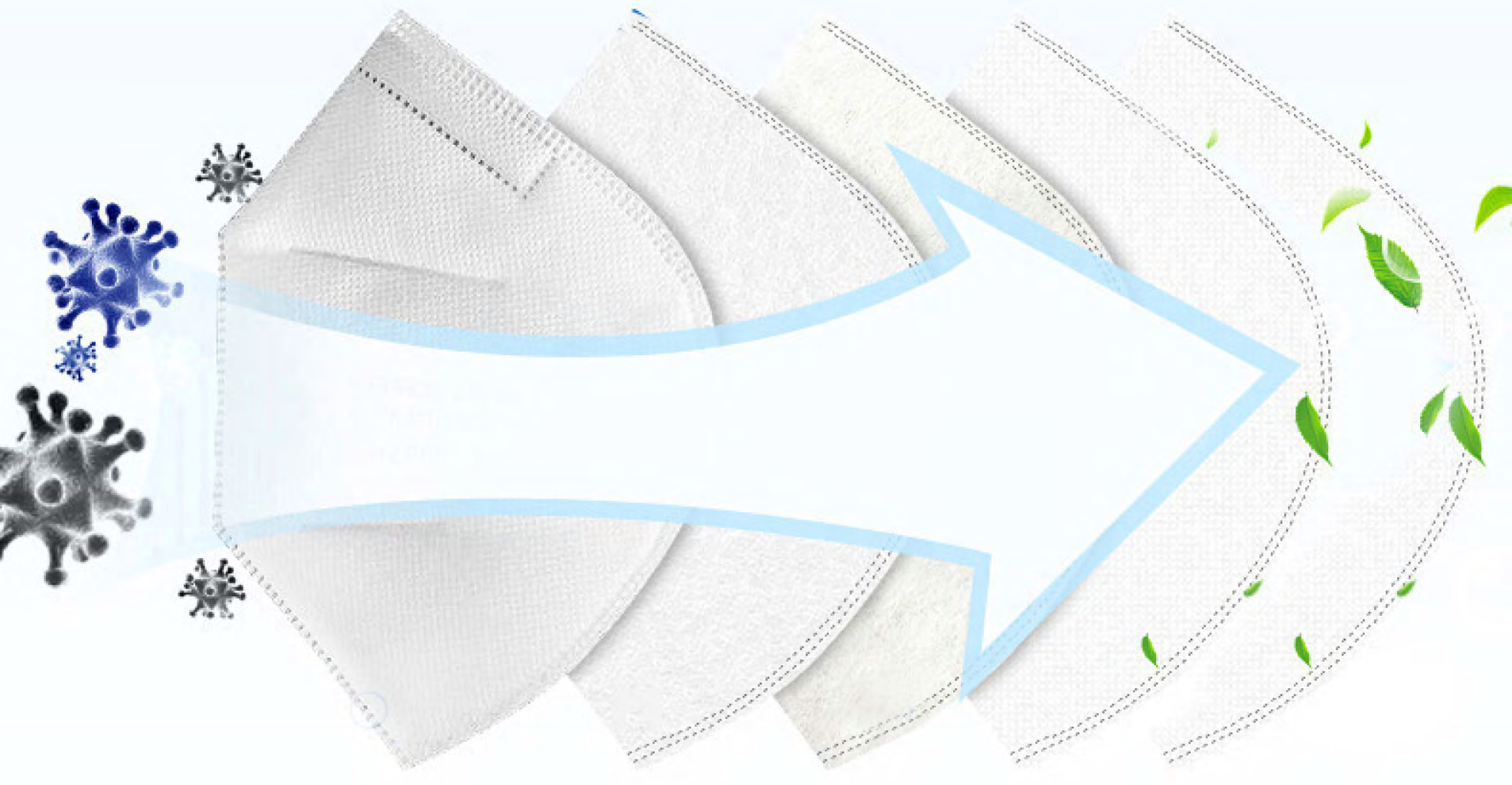
Multilayer protection

Do not use if the package is damaged

Structural components

The product consists of mask body,nose clip and mask belt.The mask itself is composed of non-woven fabric and filtration material.





Dimensions and display drawings

Product Packing

Box Size:155x127x135mm

Carton Size: 655x325x290mm

Volume: 0.07m^3

Product Qualification

★ Business license ★

立人

示 示例行条例》第十条的规定向社会公示企业信息。

登记机关

2020年 04月 16日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

★ Type II medical device business record certificate ★

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 202042965 号

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库房地址	深圳市宝安区石岩街道应人石社区应人石社区创兆二期工业区厂房 4 栋二层
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），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，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

深圳市市场监督管理局

备案部门（公章）

备案日期：2020 年 03 月 25 日

★ FDA Authentication ★

SHT-LAB

CERTIFICATION OF REGISTRATION

2020

SHT20030

This certifies that:

MEDICAL EQUIPMENT CO., LTD.

CHINA

Was registered with US Food and Drug Administration, Center for Devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807, by Shenzhen SHT Testing Technology Co., Ltd.

Owner / Operator Number:	**10065**
Device Listing #:	**See Annex**
Expiration Date:	**Dec. 31, 2020**

SHT will confirm that such registration remains effective upon request and presentation of this certificate until the and of the calendar year stated above, unless said registration is terminated after issuance of this certificate.

SHT 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.

Pursuant to 21 CFR 807.39, "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 constitutes 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, SHT is not affiliated with the U.S. Food and Drug Administration.

Mar. 29, 2020
(Date)

Ryan MA
Lab Supervisor

Shenzhen SHT Testing Technology Co., Ltd.
Tel: 0755-23318846 Fax: 0755-23318846 http://www.sht-lab.com

CERTIFICATE OF MEDICAL DEVICE REGISTRATION

2020

This certifies that:

CO., LTD.

3rd floor, 4th building,

CHINA

Owner / Operator Number: 10065196

Proprietary Name	Listing No.	Product Code	Device Class	Establishment Operations
KN95 protective mask	D391141	MSH	2	Manufacturer, Foreign Exporter

Disclaimer:
This certificate is only notification of Medical Device Registration currently effective.
This certificate makes on other representations or warranties, nor does it make any representations or warranties to any person or entity.
This certificate will expire on: 2020-12-31

★ CE Authentication ★

Certificate ✵ Сертификат ✵ 認証書 ✵ 인증서 ✵ الشهادة

Certificate NO.: LBTC202004111S

Declaration of Conformity

The following product has been tested by us with the listing standards and found in conformity with the Personal Protective Equipment Directive (EU) 2016/425. It is possible to use CE marking to demonstrate the compliance with this PPE Directive.

Report No.	:	LBTR202004
Applicant	:	**Medical Equipment Co., Ltd.**
Address	:	Community, Shiyan Street, Bao'an District, Shenzhen
Manufacturer	:	**Medical Equipment Co., Ltd.**
Address	:	Community, Shiyan Street, Bao'an District, Shenzhen
Product Name	:	**KN95 protective mask**
Trade Name	:	N/A
Model No.	:	ZH-12
Classification	:	FFP2
Test Standards	:	EN 149:2001+A1:2009

The referred test report(s) show that the product complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the above mentioned EU Directive. Other relevant Directives have to be observed.

After preparation of the necessary technical documentation as well as the conformity declaration, the CE marking as shown below can be affixed on the equipment.

Whereas the Manufacturer is responsible off the certification off the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market. The Manufacturer is also responsible off the internal production control to ensure the product(s) are in compliance with the essential requirements off the above mentioned Directive(s).

CE

Chief Manager

Date of Issue April 13, 2020

This statement is based on a single evaluation of the sample(s) of above mentioned product. It does not imply an assessment of the whole production.

LABTEST TECHNOLOGY LABORATORY LTD
Shengtianlong Building, Liuxian Road, Bao'an, Shenzhen, CHINA. Tel:+86-755-23721065, http://www.labtest.cc

★ Quality management system certificate ★

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No.：18720Q0263R0S

SHENZHEN SHENDA INTERNATIONAL CERTIFICATION CO.,LTD 深圳市深大国际认证有限公司 SDIC

We hereby certify that

Medical Equipment

Co., Ltd.

Unified social credit code/Organization code: 914403003263082913

Registered Address: [illegible]

Shenzhen, Guangdong.

by reason of its has been awarded this certificate for compliance with the standard.

GB/T19001-2016 idt ISO9001:2015

The range of certifications passed is :

Certification scope: production and sales of non-medical protective Masks

Inapplicable Clause : 8.3

Surveillance Audit (The first time)	Surveillance Audit (The second time)	Surveillance Audit (The third time)

(The validity of this certificate shall be subject to annual supervision and audit.Whether the certificate continues to be valid shall be subject to whether the supervision mark is posted)

Date of Issue:April 02,2020

Date of Expiry:April 01,2023

Issued by :

This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn)

SHENZHEN SHENDA INTERNATIONAL CERTIFICATION CO.,LTD

Address: Building 3 (3rd floor 3D) geya technology park, clock base, mashantou community, matian street,guangming new district, shenzhen

质量管理体系认证证书

证书编号：18720Q0263R0S

SHENZHEN SHENDA INTERNATIONAL CERTIFICATION CO.,LTD 深圳市深大国际认证有限公司 SDIC

兹证明

深圳市智优医疗器械有限公司

统一社会信用代码：914403003263082913

注册地址：深圳市宝安区石岩街道应人石社区应人石社区创见二期工业区厂房4栋三层

建立的质量管理体系符合以下标准要求：

GB/T19001-2016 idt ISO9001:2015

通过的认证范围如下：

非医用防护口罩的生产和销售

不适用条款：8.3

第一次监督审核	第二次监督审核	第三次监督审核

（[illegible]）

发证日期：2020年04月02日

有效期至：2023年04月01日

签发人：

本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询

深圳市深大国际认证有限公司

地址：深圳市光明新区马田街道马山头社区钟表基地格雅科技园3栋（3楼3D）