01

Certification

Certification

Certificate of Compliance

With EU Directive

Personal protective equipment(EU 2016/425)

Certificate No :

Holder :

District,shenzhen

Product : KN95 Protective Face Mask

Model(s) : SW-0615

Standards : EN 149:2001+A1:2009 FFP2 NR D

As Shown in the
Test Report Number :

Based upon the voluntary assessment of product sample and technical Construction File,the apparatus is deemed to meet the requirements of the above standards and EC directives.

Of the products are in compliance with the specification of the sample submitted for assessment and detailed in the technical file.

CE

Issued date:
Mar,18 2020

The certificate applies to the tested sample above-mentioned only and shall not imply an assessment of the whole production. It is only valid in connection with the test report above-mentioned. Copyright of this certification is owned by TXB and may not be reproduced other than in full and with the prior approval of the General Manager.

Certification of FDA Registration Service

This document provides notification of the registration number assigned to the client's establishment.

Establishment
Address:

Owner/Operator No.: 10064363
Registration No.: Waiting for assignment

Listing No.	Premarket Submission No.	Product Codes	Device Name	Activities
D378901	Exempt	MSH	Respirator, surgical	Manufacturer
D378898	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer

Certification No.:

Validity: March 25, 2020 - Dec. 31st, 2020

Certification

营业执照

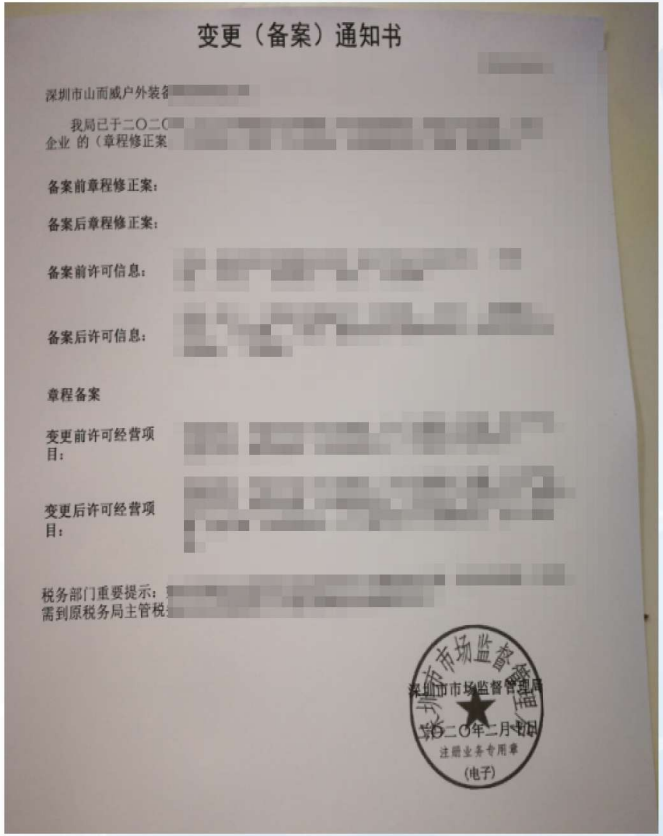
（副本）

[redacted]

[redacted]

[redacted]

Certification



变更（备案）通知书

深圳市山而威户外装备

我局已于二〇二〇

企业 的（章程修正案

备案前章程修正案：

备案后章程修正案：

备案前许可信息：

备案后许可信息：

章程备案

变更前许可经营项目：

变更后许可经营项目：

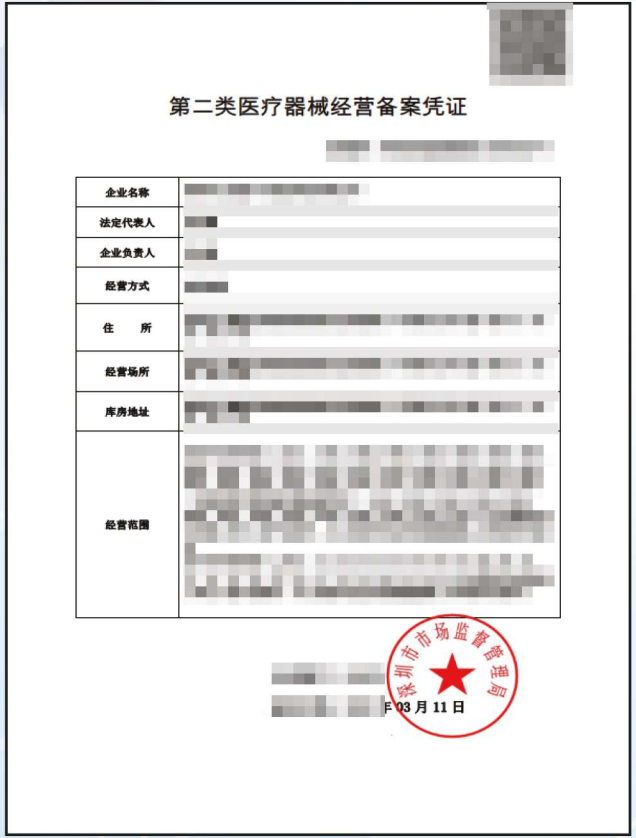
税务部门重要提示：
需到原税务局主管税

深圳市市场监督管理局

二〇二〇年二月十日

注册业务专用章

（电子）

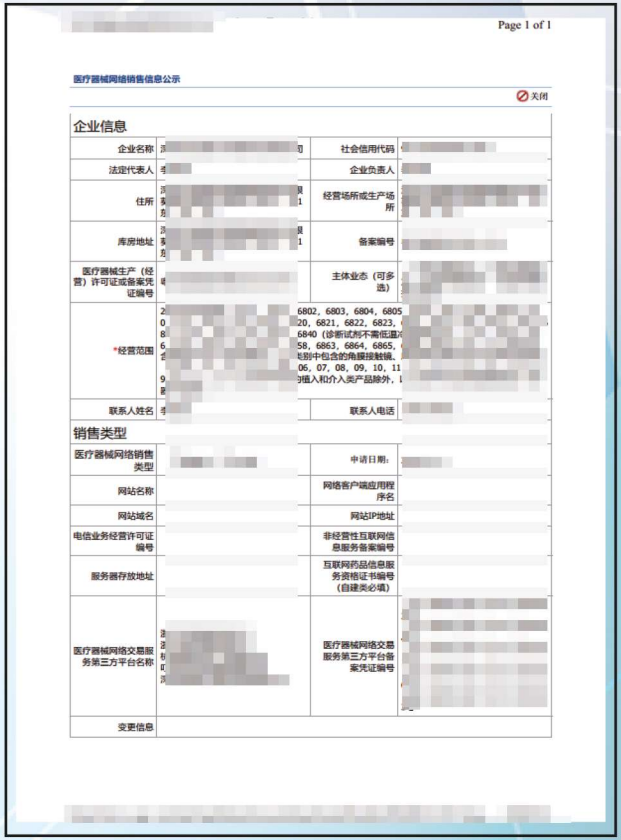


第二类医疗器械经营备案凭证

企业名称	
法定代表人	
企业负责人	
经营方式	
住　　所	
经营场所	
库房地址	
经营范围	

深圳市市场监督管理局

F 03 月 11 日



Page 1 of 1

医疗器械网络销售信息公示

关闭

企业信息

企业名称		社会信用代码	
法定代表人		企业负责人	
住所		经营场所或生产场所	
库房地址		备案编号	
医疗器械生产（经营）许可证或备案凭证编号		主体业态（可多选）	
*经营范围			
联系人姓名		联系人电话	

销售类型

医疗器械网络销售类型		申请日期：	
网站名称		网络客户端应用程序名	
网站域名		网站IP地址	
电信业务经营许可证编号		非经营性互联网信息服务备案编号	
服务器存放地址		互联网药品信息服务资格证书编号（自建类必填）	
医疗器械网络交易服务第三方平台名称		医疗器械网络交易服务第三方平台备案凭证编号	
变更信息			

Certification

[redacted]

TEST REPORT	
Prepared For :	[redacted]
Address :	[redacted]
manufacturer :	[redacted]
Address :	[redacted]
Product Name:	KN95 Protective Face Mask
Model :	SW-0615
Prepared By :	[redacted] Corp Limited

TXB RHEINLAND TESTING SERVICES CORP LIMITED CERTIFICATE

Test Date:2020-03-11

Date of Report:2020-03-18

Report No. [redacted]

Test Requested： Selected test (s) in the selected parts as requested by client

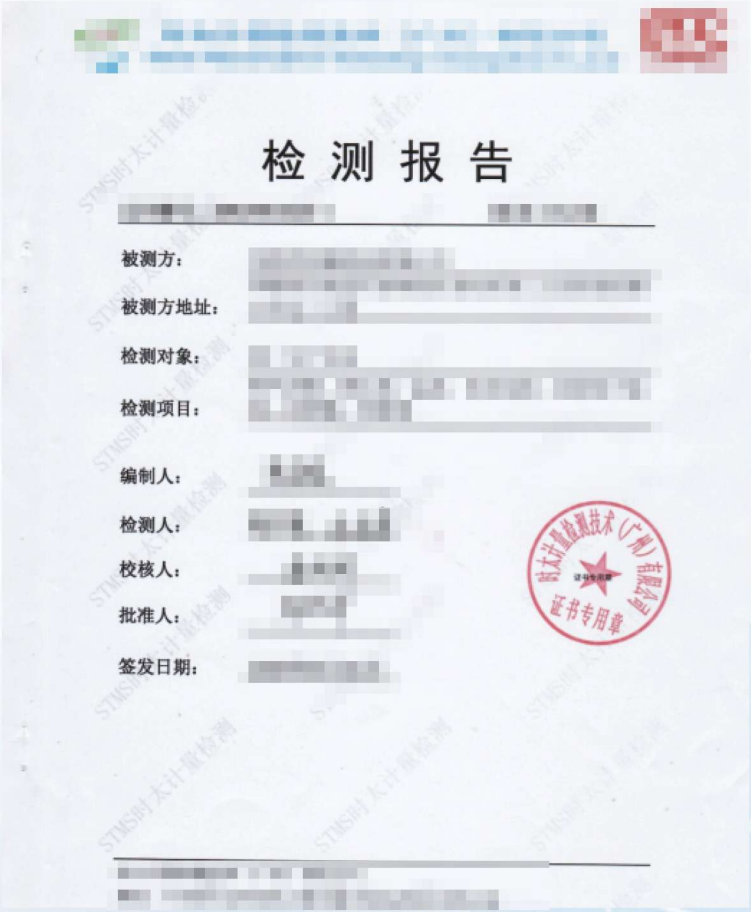
Test Method： Please refer to next page(s).
Test Result： Please refer to next page(s).

[redacted]

[redacted]

EN 149:2001+A1:2009 FFP2 NR D			
Clause	Requirement + Test	Result - Remark	Verdict
1.	Basic requirements for masks		P
	1.1 The mask should cover the snout of the wearer	Untreated sample: 1#-3# pass	
	1.2. There should be good facial adhesion		
	1.3. There must be no holes or stains on the surface.		
2.	Nose clip		P
	2.1 Masks should be equipped with nose clips	Untreated sample: 1#-3# pass	
	2.2 The nose clip should be adjustable		
3.	Mask band		P
	3.1 should be easily adjusted with 10N or more	Untreated sample: 1# 36.2N 2# 36.3N 3# 36.8N 4# 36.7N	
4.	Filtration efficiency		P
	4.1 The untreated sample is greater than or equal to 99.48%,	96.84%	
	4.2 Pretreated samples need to be greater than or equal to 99.50%	96.63%	
5	Resistance to airflow		P
	5.1 343.2Pa or less, temperature: 23 Relative humidity: 34.6%	Untreated sample: 1# 94.4 2# 96.8 3# 94.8	
6	Synthetic blood penetration		P
	6.1 There should be no infiltration on the inside of the mask	1#-5# No penetration in the mask	
7.	Surface moisture resistance		P
	7.1 Moisture resistance is greater than or equal to 3	4	
8	Flame retardant performance, afterflame time		P
	8.1 5S or more	1s	

Certification



检 测 报 告

被测方：

被测方地址：

检测对象：

检测项目：

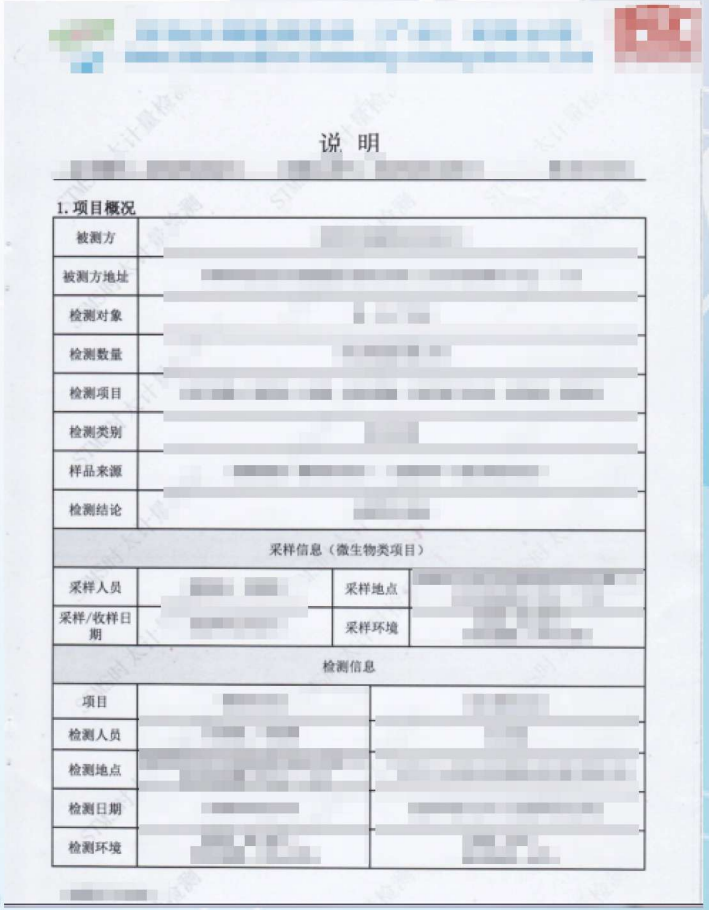
编制人：

检测人：

校核人：

批准人：

签发日期：



说 明

1. 项目概况

被测方	
被测方地址	
检测对象	
检测数量	
检测项目	
检测类别	
样品来源	
检测结论	

采样信息（微生物类项目）

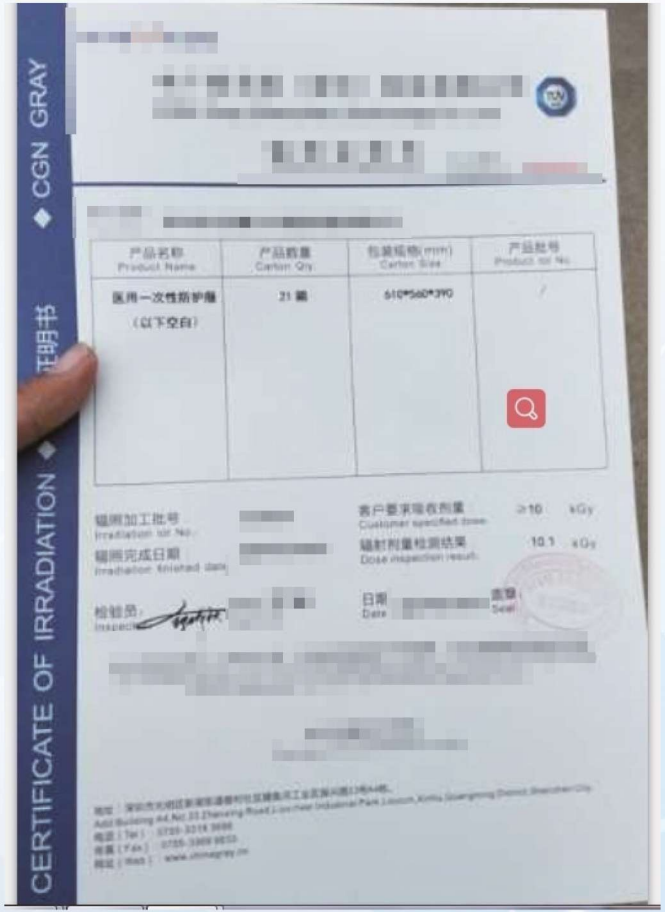
采样人员		采样地点	
采样/收样日期		采样环境	

检测信息

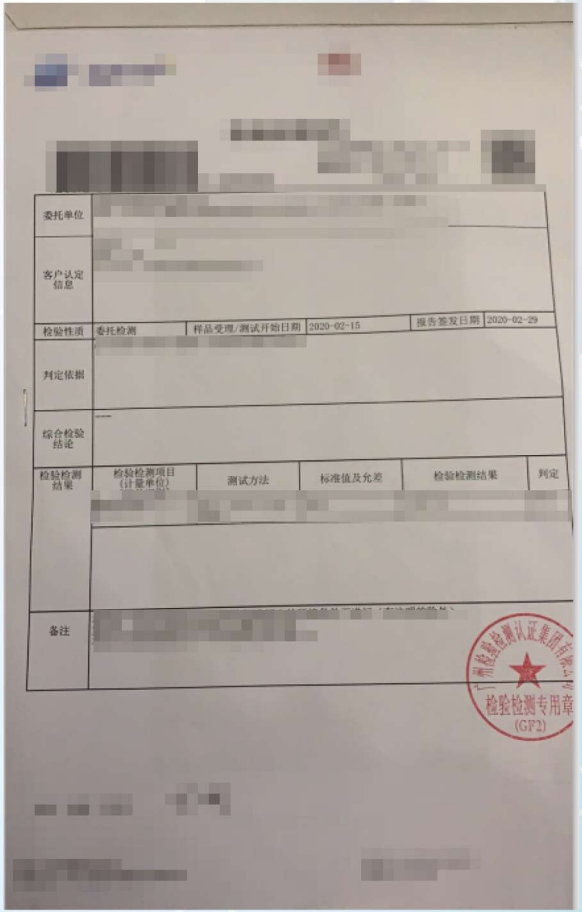
项目		
检测人员		
检测地点		
检测日期		
检测环境		

Clean workshop cleanliness test report

Certification



Irradiation certificate

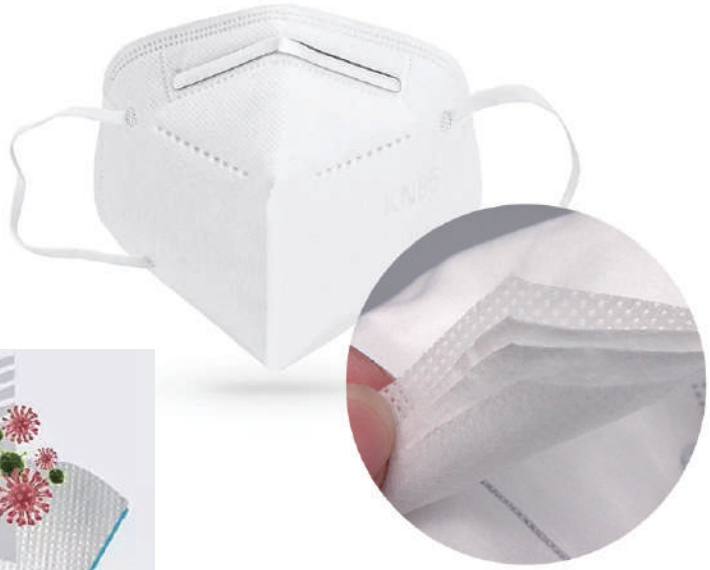


Sterility test report

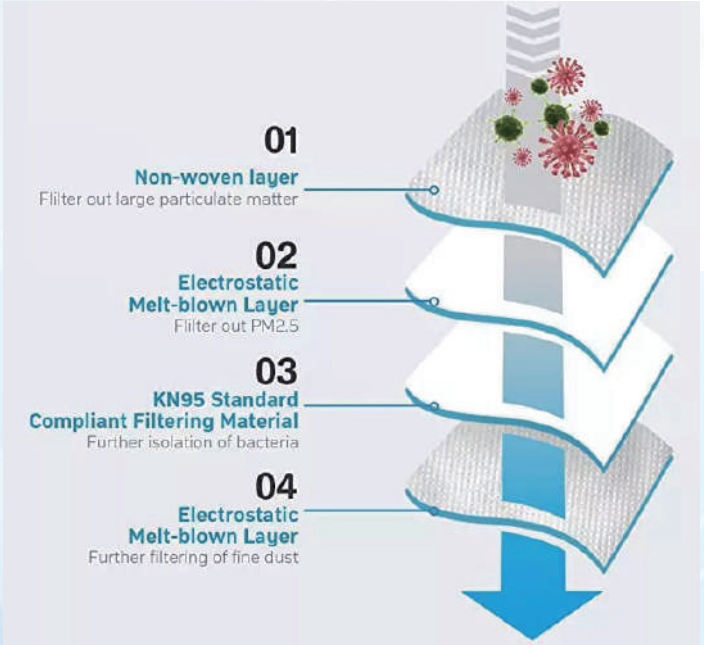
02

Sample display

Sample display



4 Filtering Layers Melt-down Material
Filtration Efficiency > 95 %



Sample display

Sample display