1. Company Profile

2. CE Certification

3. CE TestReport

4. FDA Certification

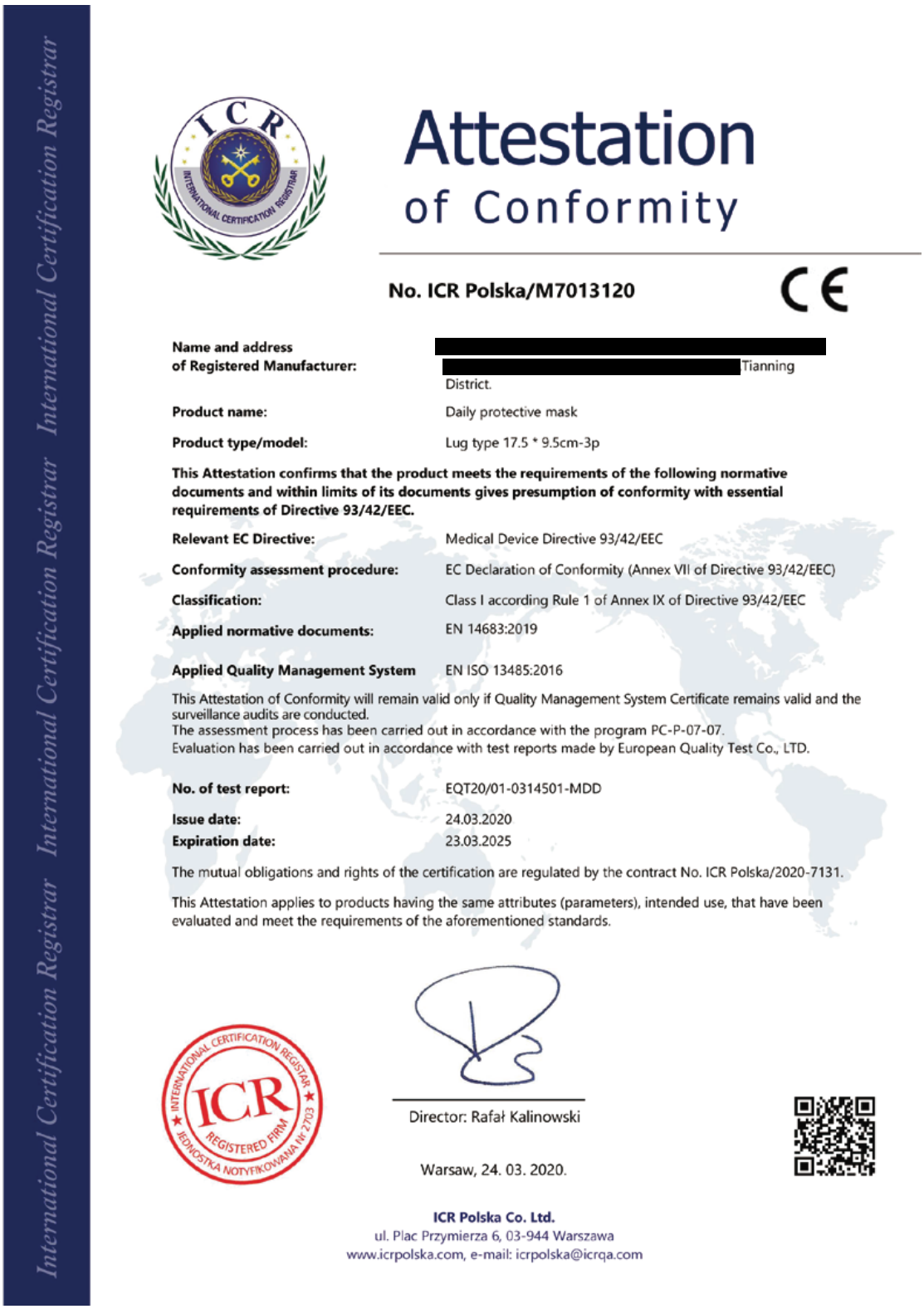
5. Mask Test Report

6. Mask Packaging

7. Carton Packaging

2. CE Certification

(Protective Mask)



International Certification Registrar International Certification Registrar International Certification Registrar

Attestation of Conformity

No. ICR Polska/M7013120

CE

Name and address of Registered Manufacturer:	[redacted] Tianning District.
Product name:	Daily protective mask
Product type/model:	Lug type 17.5 * 9.5cm-3p

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	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
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 reports made by European Quality Test Co., LTD.

No. of test report:	EQT20/01-0314501-MDD
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-7131.

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

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

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

2. CE Certification
(Disposable Medical Mask)

International Certification Registrar International Certification Registrar International Certification Registrar

Attestation
of Conformity

No. ICR Polska/M7013220 CE

Name and address of Registered Manufacturer:	[redacted]ianning District.
Product name:	Disposable medical mask
Product type/model:	Lug type 17.5 * 9.5cm-3p

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	EN ISO 13485:2016

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
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 reports made by European Quality Test Co., LTD.

No. of test report:	EQT20/01-0314500-MDD
Issue date:	24.03.2020
Expiration date:	23.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-7132.

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

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.

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

3. CE Test Report
(Protective Mask)

CE
TEST REPORT

BS EN 14683 : 2019

For

Disposable Protective Mask

Model: FRK2020001

Report No.: EQT20/01-0314501-MDD

Date of Issue: Mar. 24, 2020

Prepared For

[redacted]

[redacted]**Tianning District.**

Prepared By

Guang Dong WFTC Technical Services Limited.

[redacted]**China**

TEST REPORT
EN 149:2001+A1:2009
Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Report reference No.	: EQT20/01-0314501-MDD
Tested by	: Samliu
Review by (+ Signature).	: Yemig
Approved by (+ signature)	: Ray Zhou
Date of issue	: Mar. 24, 2020
Contents	: Total 9 pages

Testing laboratory

Name	: [redacted]
Address	:
Testing location	: Same as above

Application

Name	: [redacted]
Address	:

Manufacturer

Name	: [redacted]
Address	:

Test specification

Standard	: BS EN 14683: 2019
Test procedure	: CE
Procedure deviation	: N/A
Non-standard test method	: N/A

Test Report Form/blank test report

Test Report Form No.	: ENC149-A2
TRF originator.	: ENC

Test item

Description	: Daily protective mask
Brand name	:
Model	:

Sample Description and Number	Test Items	Limit			Test Results		ReferenceMethods
		Type I	Type II	Type IIR			
R783977QA Disposable Medical Face Mask	Bacterial filtration efficiency(BFE), %	≥95	≥98	≥98	No.1	99.6	BS EN 14683: 2019
					No.2	99.6	
					No.3	99.7	
					No.4	99.6	
					No.5	99.7	
	Differential pressure, Pa/cm^2	<40	<40	<60	No.1	31.1	BS EN 14683: 2019
					No.2	30.2	
					No.3	29.8	
					No.4	30.1	
					No.5	30.4	
	Splash resistance pressure, kPa	/	/	≥16.0	Not penetrate		BS EN 14683: 2019
	Microbial cleanliness, cfu/g	≤30	≤30	≤30	<1		BS EN 14683: 2019

3. CE Test Report
(Disposable Medical Mask)

CE
TEST REPORT

BS EN 14683: 2019

For

Disposable medical mask

Model: FRK2020001

Report No.: EQT20/01-0314500-MDD

Date of Issue: Mar. 24, 2020

Prepared For

[redacted]

[redacted]**Tianning District.**

Prepared By

Guang Dong WFTC Technical Services Limited.

[redacted]**China**

TEST REPORT
EN 149:2001+A1:2009
Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Report reference No.	: EQT20/01-0314500-MDD
Tested by	: Samliu
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Contents	: Total 9 pages

Testing laboratory

Name	: [redacted]
Address	:
Testing location	: Same as above

Application

Name	: [redacted]
Address	:

Manufacturer

Name	: [redacted]
Address	:

Test specification

Standard	: BS EN 14683：2019
Test procedure	: CE
Procedure deviation	: N/A
Non-standard test method	: N/A

Test Report Form/blank test report

Test Report Form No.	: ENC149-A2
TRF originator.	: ENC

Test item

Description	: Disposable medical mask
Brand name	:
Model	:

Sample Description	Disposable medical mask	Sample Specification	——
Applicant	[redacted]	Trade Mark	——
Received Date	2020-03-17	Manufacturing Date or Lot No.	——
Test Date	2020-03-17~2020-03-27	Sample Grade	——
Sample Quantity	40	Test Type	Commissioning Test
Sample Status	Packing Intact	Test Environment	To meet the requirements
Test Items	See the next page		
Reference Methods	See the next page		
Main Instruments	Electric Heating Constant Temperature Incubator、 Bacterial filtration efficiency detector etc.		
Note	Limit on： BS EN 14683： 2019		

4. FDA CERTIFICATION

SHT–LAB

CERTIFICATION OF REGISTRATION

2020

SHT2003020FD

This certifies that:

[redacted]

[redacted] **Jiangsu, 213000, 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:	**10063607**
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.

FDA

SHENZHEN SHT TESTING TECHNOLOGY CO., LTD. SHT

Mar. 24, 2020

(Date)

Ryan MA

Lab Supervisor

SHT-LAB

Annex to Device Listing #:

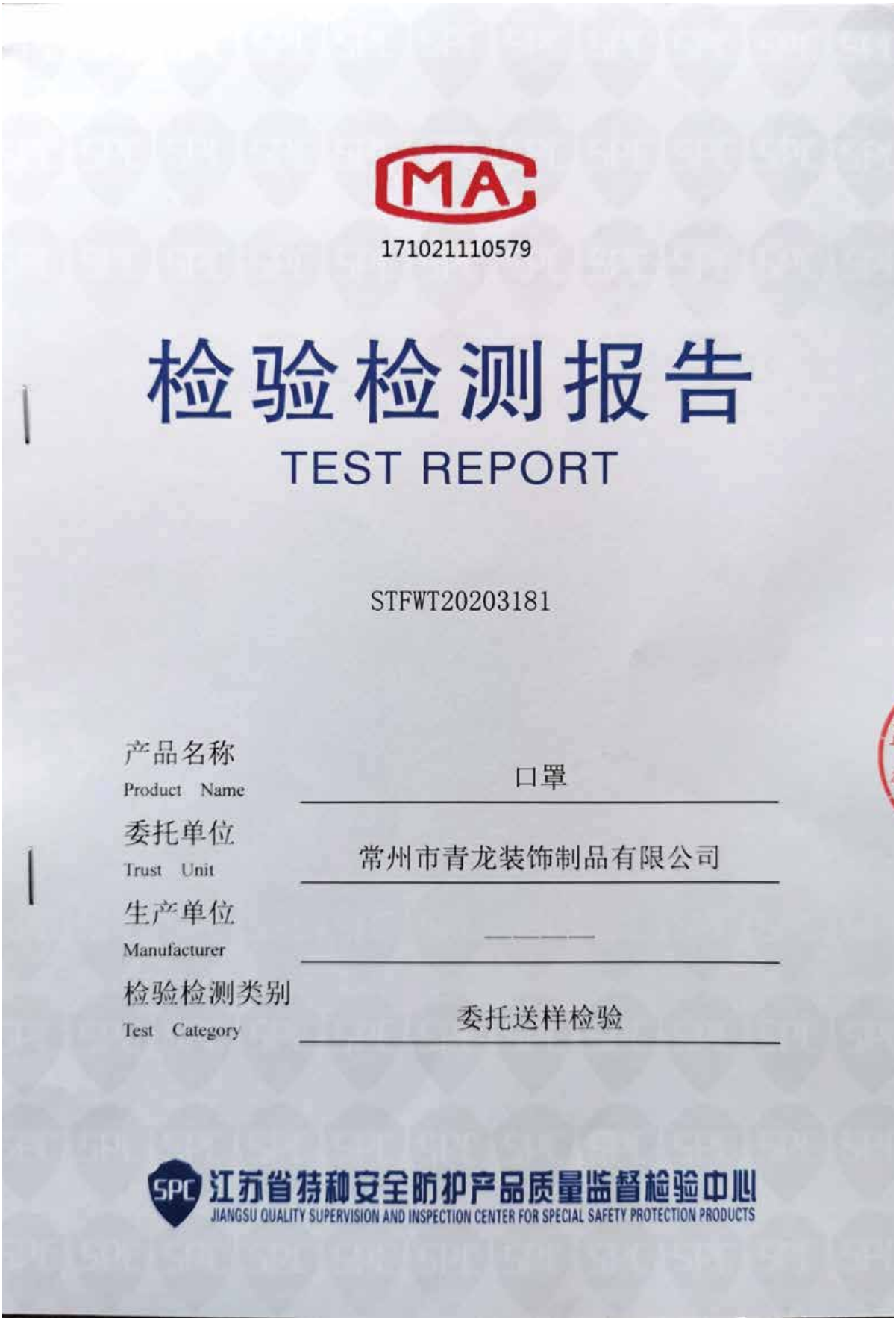
Proprietary Name	Product Codes	Device Class	Listing Number	Establishment Operations
Daily protective mask	KHA	1	D376791	Manufacturer

FDA

Mar 24, 2020
(Date)

Ryan MA
Lab Supervisor

5. Mask Test Report
(Protective Mask)



CMA
171021110579

检验检测报告
TEST REPORT

STFWT20203181

产品名称 Product Name	口罩
委托单位 Trust Unit	常州市青龙装饰制品有限公司
生产单位 Manufacturer	———
检验检测类别 Test Category	委托送样检验

SPC 江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

防伪查询

STFWT20203181

产品名称 Product Name	口罩	规格型号 Specification Type	——
		商 标 Trademark	——
委托单位 Trust Unit	常州市青龙装饰制品有限公司	电 话 Tel	13809071119
生产单位 Manufacturer	——	样品等级 Sample Grade	——
样品数量 Sample Quantity	50 只	送样日期 Sample Receiving Date	2020-03-05
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	——
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	T/CTCA7-2019《普通防护口罩》 GB 15979-2002《一次性使用卫生用品卫生标准》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 T/CTCA7-2019 标准规定的要求。 签发日期： 2020-03-20 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

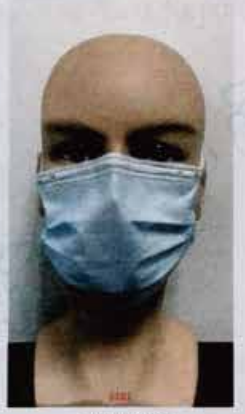
批 准： 陈敏 Approver　　审 核： 吴高高 Examiner　　主 检： 未秀萍 Majortester

检 验 检 测 结 果
Testing Results

STFWT20203181

序号 Serial	检验检测项目 Test Items		单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	微生物指标	细菌菌落总数	CFU/g	≤200	12	合 格
		大肠菌群	——	不得检出	未检出	
		金黄色葡萄球菌	——	不得检出	未检出	
		绿脓杆菌	——	不得检出	未检出	
		溶血性链球菌	——	不得检出	未检出	
		真菌菌落总数	CFU/g	≤100	8	

样 品 图 片



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The Institute Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu
检验检测机构监督电话：0523-86989901
The Institute Complain Tel:0523-86989901
检验检测机构业务电话：0523-86989959
The Institute Businese Tel:0523-86989959
检验检测机构传真：0523-86989939
The Institute Fax:0523-86989939
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检验检测机构网址：www.jstfzx.com
The Institute Web:www.jstfzx.com
检验检测机构邮箱：17358898887@qq.com
The Institute E-mail:17358898887@qq.com

5. Mask Test Report
(Disposible Medical Mask)

CMA
171021110579

检验检测报告
TEST REPORT

STFWT20203180

产品名称 Product Name	口罩
委托单位 Trust Unit	常州市青龙装饰制品有限公司
生产单位 Manufacturer	[redacted]
检验检测类别 Test Category	委托送样检验

SPC 江苏省特种安全防护产品质量监督检验中心
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

检 验 检 测 报 告

Test Report

防伪查询

STFWT20203180

产品名称 Product Name	口罩	规格型号 Specification Type	——
		商 标 Trademark	——
委托单位 Trust Unit	常州市青龙装饰制品有限公司	电 话 Tel	13809071119
生产单位 Manufacturer	[redacted]	样品等级 Sample Grade	——
样品数量 Sample Quantity	50 只	送样日期 Sample Receiving Date	2020-03-05
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	——
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	T/CTCA7-2019《普通防护口罩》 YY 0469-2011 《医用外科口罩》 GB 2890-2009《呼吸防护 自吸过滤式防毒面具》 GB/T 7573-2009《纺织品 水萃取液 pH 值的测定》 GB/T 2912.1-2009《纺织品 甲醛的测定 第 1 部分:游离和水解的甲醛(水萃取法)》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 T/CTCA7-2019 标准规定的要求。 签发日期：2020-03-18 SignatuimDate		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批 准：Approver 陈敏 审 核：Examiner 吴高高 主 检：Majortester 蔡燕文

检 验 检 测 结 果
Testing Results

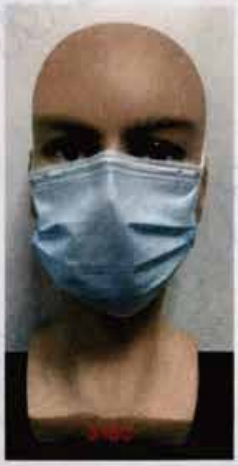
STFWT20203180

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	外观要求	——	口罩表面不应有破损、油污斑渍、变形及其他明显的缺陷。	口罩表面无破损、油污斑渍、变形及其他明显的缺陷。	合 格
2	通用要求	——	口罩应能安全牢固地护住口、鼻。 口罩不应存在可触及的锐利角和锐利边缘，不应对佩戴者构成伤害。 口罩应便于佩戴和摘除，在佩戴过程中无明显的压迫感或压痛现象，对头部活动影响较小。	口罩能安全牢固地护住口、鼻。 口罩不存在可触及的锐利角和锐利边缘，未对佩戴者构成伤害。 口罩便于佩戴和摘除，在佩戴过程中无明显的压迫感和压痛现象，对头部活动影响较小。	合 格
3	口罩下方视野	——	≥60°	65°	合 格
4	口罩带及口罩带与口罩体的连接处断裂强力	N	≥10	1#：试样断裂强力不小于 10N 2#：试样断裂强力不小于 10N 3#：试样断裂强力不小于 10N	合 格
5	pH 值	——	4.0-7.5	6.1	合 格
6	甲醛含量	mg/kg	≤20	未检出	合 格
7	细菌过滤效率/%（BFE）	——	≥95	96.2	合 格
8	通气阻力	Pa	≤80	1#：63 2#：65 3#：61	合 格
9	颗粒过滤效率/%（PFE）	——	≥80	1#：87.7 2#：88.0 3#：85.8	合 格
备注	甲醛含量小于 20 mg/kg，试验结果报告未检出。				

检 验 检 测 结 果
Testing Results

STFWT20203180

样 品 图 片



以下空白

注 意 事 项

1、检验检测报告无“检验检测报告专用章”或检验检测单位公章无效。

2、复制检验检测报告未重新加盖“检验检测报告专用章”或检验检测单位公章无效。

3、检验检测报告无主检、审核、批准人签字无效。

4、检验检测报告涂改无效。

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2. The Reproduction Is Invalid If Without Being Confirmed By “The Text Report Special Seal” Or The Official Seal Of The Institute.
3. This Report Is Invalid If Without Signature Of The Major Tester And The Examiner And The Approver.
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The Institute Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu
检验检测机构监督电话：0523-86989901
The Institute Complain Tel:0523-86989901
检验检测机构业务电话：0523-86989959
The Institute Businese Tel:0523-86989959
检验检测机构传真：0523-86989939
The Institute Fax:0523-86989939
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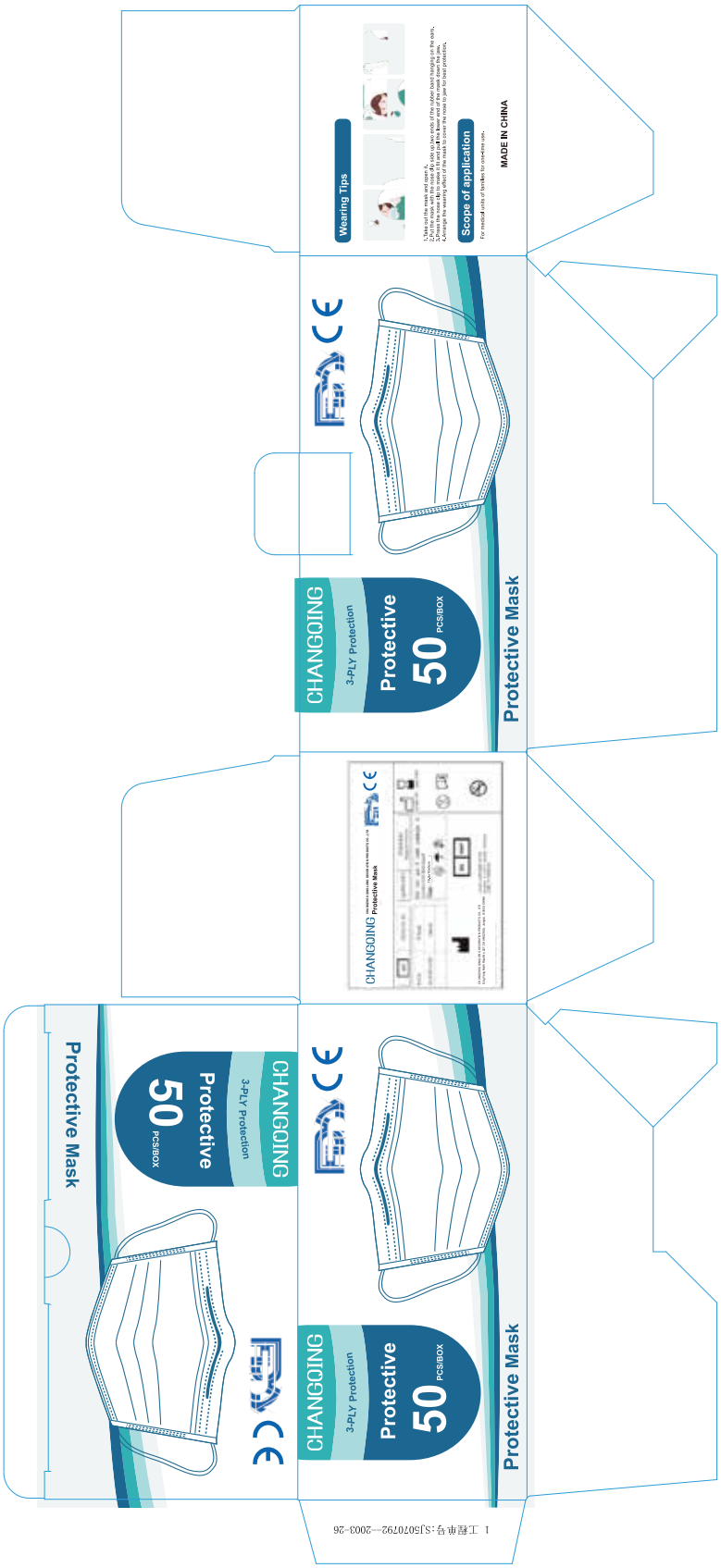
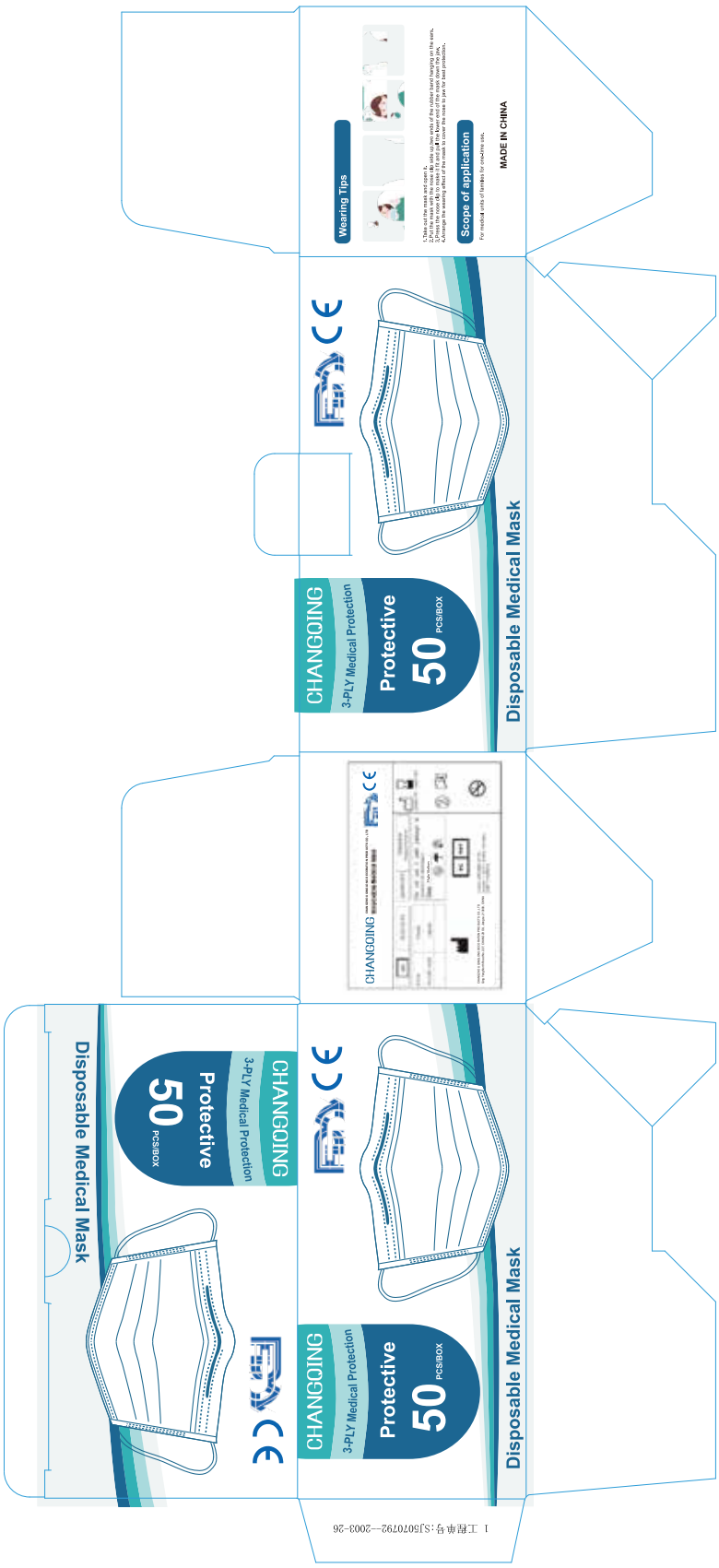
The Institute Web:www.jstfzx.com
检验检测机构邮箱：1735889887@qq.com
The Institute E-mail:1735889887@qq.com

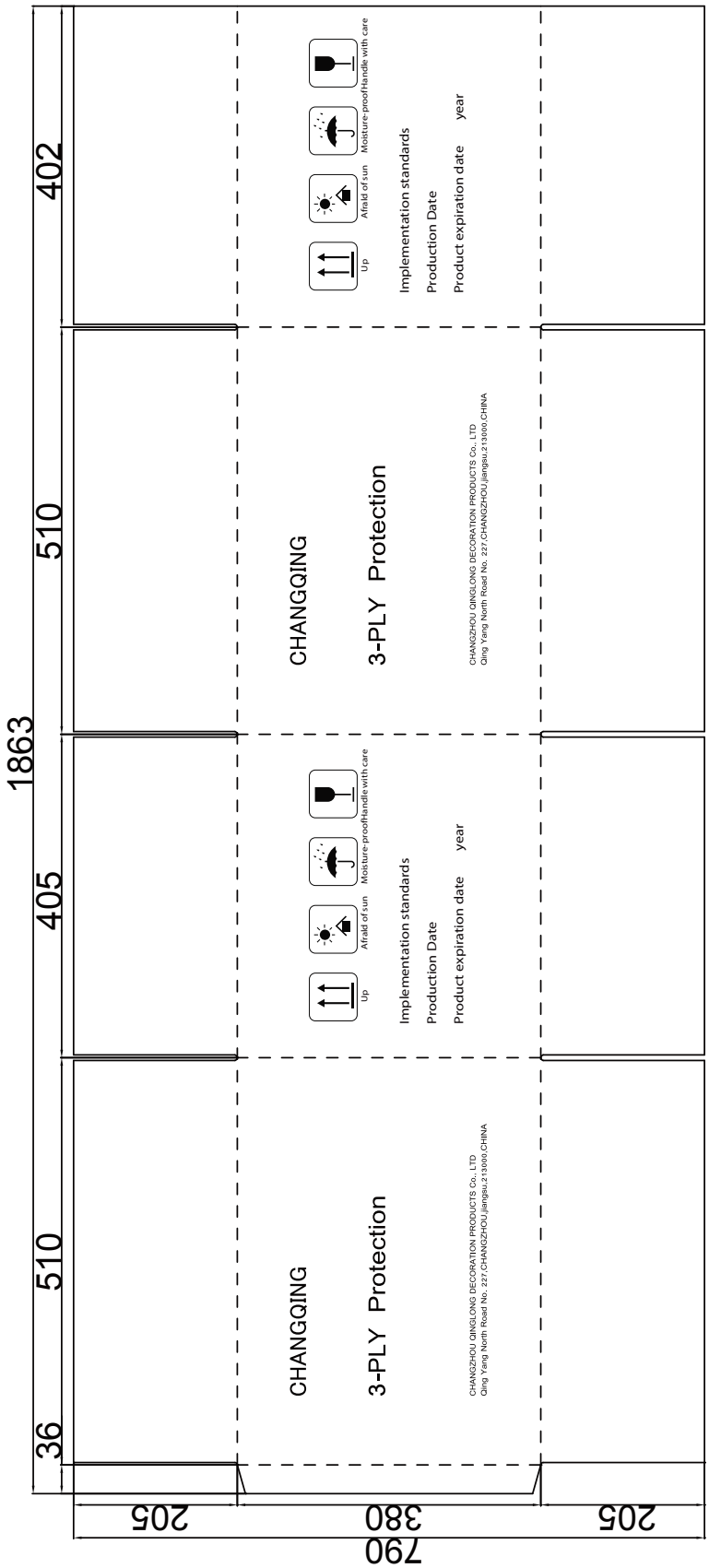
6. Mask Packaging
(Protective Mask)



6. Mask Packaging
(Disposable Medical Mask)



7. Carton Packaging
(Protective Mask)



7. Carton Packaging
(Disposable Medical Mask)