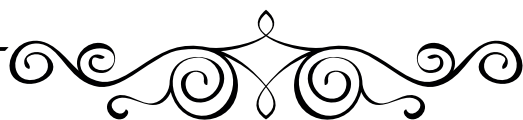


日用口罩



10片/包*5包/盒

产品资料

四川制药制剂有限公司

www.sczyzj.com



营业执照

(副本)

统一社会信用代码

91510100777457202W



扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名称 四川制药有限公司

注册资本 捌仟万元整

类型 其他有限责任公司

成立日期 2005年07月14日

法定代表人 沈山

营业期限 2005年07月14日 至 2035年07月13日

经营范围

生产、销售粉针剂（青霉素类、头孢菌素类），冻干粉针剂、硬胶囊剂（含青霉素类、头孢菌素类），片剂（含青霉素类、头孢菌素类），原料药（依折麦布、盐酸决奈达隆、依达拉奉），干混悬剂，生产、销售保健品；销售化工原料、包装材料；医疗器械生产；第一类医疗器械销售、第二类医疗器械销售；第三类医疗器械经营；生产、销售劳保用品、消毒用品、医用防护用品、卫生用品、服装、鞋帽、手套；医药产品研发项目、投资及项目咨询（不得从事非法集资、吸收公众资金等金融活动）；货物进出口、技术进出口；货物仓储。（依法须经批准的项目，经相关部门批准后方可开展经营活动）。

住所 成都市高新西区百叶路18号

登记机关



2020

年4月27日



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: Sichuan Pharmaceutical, Inc

Add: No. 18 Baiye Road, Hi-Tech West Zone, Chengdu, Sichuan Province, China

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

The Owner/ Operator Number for this Registration is: 10069249

Listing No	Code	Premarket Submission NO.	Device Name
D390202	QKR	Enforcement	Disposable Medical face Mask, Disposable Mask, Disposable Protective Mask
D390204	LYU	/	Medical Surgical Mask

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed 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 Food and Drug Administration.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Apr. 12, 2020

Date of expiration: Dec. 31, 2020

SH OFFICE

TEL:0086-21-50313932 Boyle Wang Phone:0086-18930777676 info@truthful.com.cn

ABMED SERVICE INC.

36 South 18th Avenue, Suite A Brighton USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

EU Declaration of Conformity

Manufacturer: SICHUAN PHARMACEUTICAL.INC
18 Baiye road, Gaoxin West district, Chengdu City,
Sichuan Province, the Peoples Republic of China

SRN:
European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN:
Product Name: Disposable medical face mask/ Disposable mask/
Disposable Protective Mask

Specification: Flat/ Foldable

GMDN Code: 35177

UMDN Code: 12-458

UDI-DI:

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY
following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

Signature:

Position: Deputy General Manager

Name: Ping Liu

Place/date: SICHUAN PHARMACEUTICAL.INC 2020.03.17

EC Declaration of Conformity

Manufacturer:

SICHUAN PHARMACEUTICAL.INC

18 Baiye road, Gaoxin West district,
Chengdu City, Sichuan Province, the
Peoples Republic of China

Whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable medical face mask
Disposable mask
Disposable Protective Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

SICHUAN PHARMACEUTICAL.INC
18 Baiye road, Gaoxin West district, Chengdu City, Sichuan
Province, the Peoples Republic of China

SICHUAN PHARMACEUTICAL.INC 2020.03.17

Place, date

Ping Liu

Legally binding signature, Function

EU Declaration of Conformity

Manufacturer: SICHUAN PHARMACEUTICAL INC
18 Baiye road, Gaoxin West district, Chengdu City,
Sichuan Province, the Peoples Republic of China

SRN:
European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN:
Product Name: Disposable medical face mask/ Disposable mask/
Disposable Protective Mask

Specification: Flat/ Foldable

GMDN Code: 35177

UMDN Code: 12-458

UDI-DI:

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY
following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

Signature:

Position: Deputy General Manager

Name: Ping Liu

Place/date: SICHUAN PHARMACEUTICAL INC 2020.03.17



EC Declaration of Conformity

Manufacturer:

SICHUAN PHARMACEUTICAL.INC

18 Baiye road, Gaoxin West district,
Chengdu City, Sichuan Province, the
Peoples Republic of China

Whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

**Disposable medical face mask
Disposable mask
Disposable Protective Mask**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

SICHUAN PHARMACEUTICAL.INC
18 Baiye road, Gaoxin West district, Chengdu City, Sichuan
Province, the Peoples Republic of China

SICHUAN PHARMACEUTICAL.INC 2020.03.17

Place, date

Legally binding signature, Function



Verification of CE Registration

Certificate No.: C-SP-202003-01

This is to certify that during the examination of the Technical Documentation provided by the manufacturer:

Name: SICHUAN PHARMACEUTICAL INC.

Address: 18 Baiye Road, Gaoxin West District, Chengdu City, Sichuan Province, China

On its product as follows:

Product Name: Disposable medical face mask/ Disposable mask/ Disposable Protective Mask

Classification: Class I.

Technical Documentation number: SP/CE01-01

No Non-compliance according to the requirements of the Medical Device Regulation (EU) 2017/745 Annex II and Annex III was detected, and the aforementioned device complies with the Regulation including all General Safety and Performance Requirements defined in Annex I.

The manufacturer has provided the EU Declaration of Conformity according to the Medical Device Regulation (EU) 2017/745 - article 19 requirements, confirming that this medical device, as stipulated above, is fulfilling the applicable requirements of the Medical Device Regulation (EU) 2017/745.

The notification of aforementioned device has been completed by the European Representative in Germany. The German Competent Authority is notified of the manufacturer's medical devices and has allocated registration.

Issue Date: Mar. 22, 2020

Date of expiry: Mar. 21, 2025


SIGNATURE



ABMED SERVICE INC.
Room 608, No. 738 Shangcheng Rd., Pudong, 200120 Shanghai, China
E-mail: info@abmed.com.cn



四川省医疗器械检测中心

检测结果通知书

报告编号: QX2020H02324



样品名称	日用口罩	型号规格	175mm×95mm×3层
委托单位	四川制药制剂有限公司	样品批号	20200308
		生产日期	2020.03.11
受检单位	\	出厂编号	\
生产单位	四川制药制剂有限公司	包 装	\
商 标	\	样品状态	\
检验类别	合同检验	抽样地点	\
抽样方法	\	样品数量	60 只
抽样基数	\	抽/送样者	\
收检日期	2020年03月12日	检验地点	汇都分部
样品效期	\	检验日期	2020年03月12日~2020年03月15日
检验依据	四川制药制剂有限公司日用口罩产品技术要求Q/SCZY/T-2020-04		
检验项目	部分检验		
检验结论	本品按四川制药制剂有限公司日用口罩产品技术要求Q/SCZY/T-2020-04检验, 所检项目结果见附页。		
备 注	\		

检验人:

审核人:

签发人:

签发日期: 2020年3月15日

检测结果附页

报告编号: QX2020H02324

样品名称	日用口罩	样品数量	60 只
生产单位	四川制药制剂有限公司	批 号	20200308

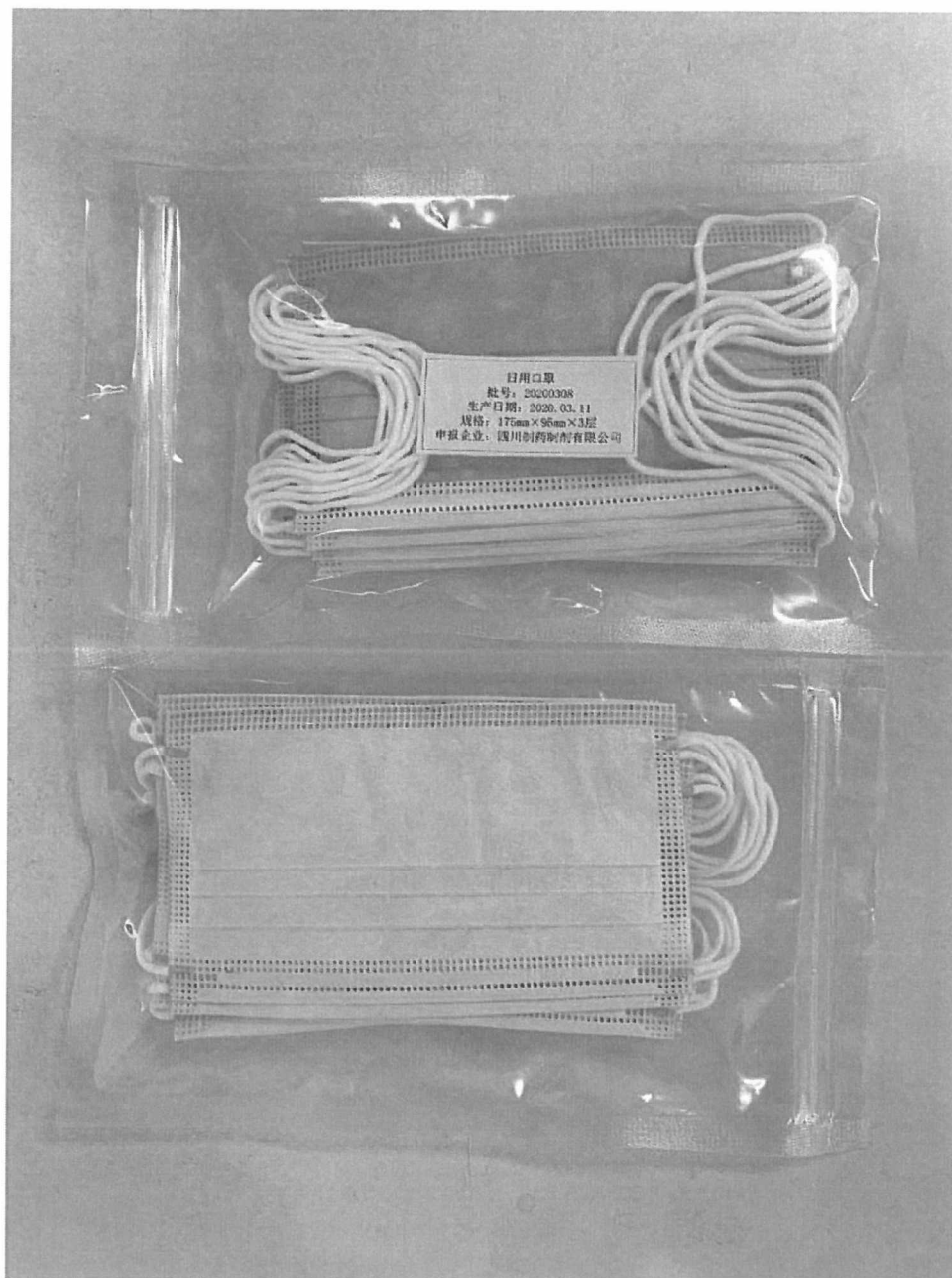
检验项目	技术要求	检测结果
2. 性能指标		
2.1 外观	表面整洁, 形状完好, 不应有破损、污渍	表面均整洁、形状完好, 均没有破损、污渍
2.2 结构与尺寸	口罩佩戴好后, 应能罩住佩戴者鼻、口至下颌 应符合设计尺寸, 公差不得超过 $\pm 5\%$, 即应为 $(175\text{mm} \pm 8.75\text{mm}) \times (95\text{mm} \pm 4.75\text{mm})$	均能罩住佩戴者鼻、口至下颌 (167.27~168.42) mm \times (95.00~95.30) mm
2.3 鼻夹	配有鼻夹, 鼻夹具有可调节性 鼻夹长度应不小于 8.0cm	均配有鼻夹, 鼻夹均具有可调节性 最小值: 9.8cm
2.4 口罩带	应戴取方便 每根口罩带与口罩体连接点的断裂强力应不小于 5N	均戴取方便 均大于 5N
2.5 细菌过滤效率 (BFE)	细菌过滤效率应不小于 95%	最小值: 99%
2.6 颗粒过滤效率 (PFE)	对非油性颗粒的过滤效率应不小于 90%	最小值: 95%
2.7 压力差 (Δp)	口罩两侧面进行气体交换的压力差 Δp 应不大于 $49\text{Pa}/\text{cm}^2$	最大值: $28\text{Pa}/\text{cm}^2$

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检测结果附页

报告编号: QX2020H02324

照片页 (一)

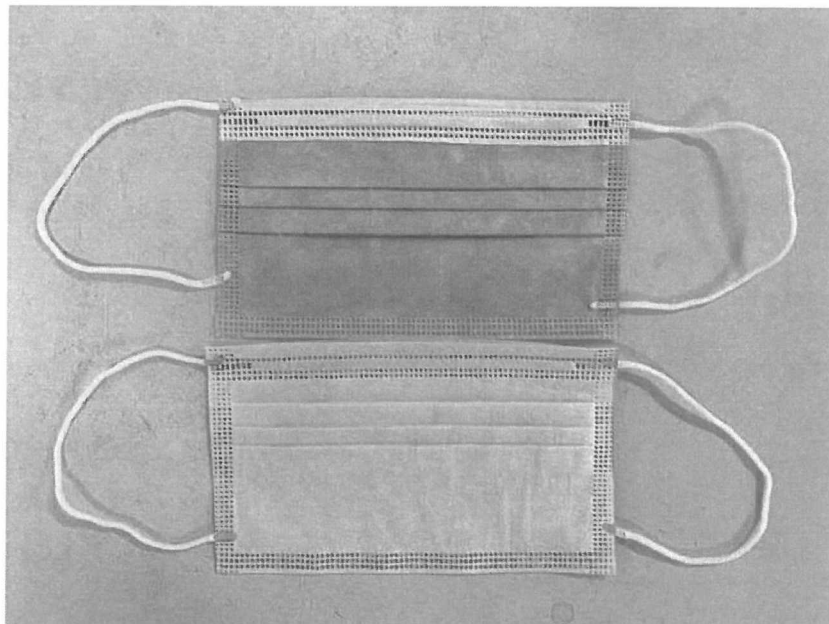


照片描述: 样品及样品信息

检测结果附页

报告编号: QX2020H02324

照片页 (二)



照片描述: 样品及样品信息

委托方信息	联系人: 彭海燕	电话: 13678186912
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参
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图
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(2)

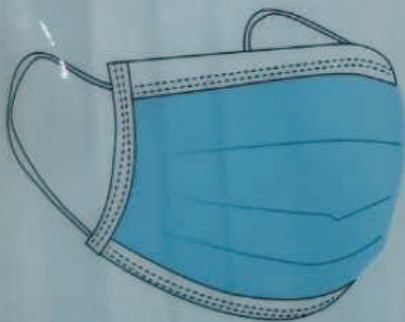
好药师
HAIYAO

本品在十万级洁净车间内生产

日用口罩

DISPOSABLE MASK

长方形 耳挂式 (175mm×95mm×3层)



10片/袋 5袋/盒

适用于日常生活中空气污染环境下佩戴的口罩。

四川新特制药有限公司
SICHUAN XINTE PHARMACEUTICAL, INC.

【产品名称】日用口罩
【型号、规格】长方形耳挂式
175mm×95mm×3层
【结构与组成】本产品由口罩体、鼻梁、口罩带组成。口罩体由熔喷无纺布和超细纤维无纺布为主要原料组成。
【适用范围】适用于在日常生活空气中污染环境下佩戴的口罩。

【使用方式】
1. 打开包装取出口罩，检查口罩是否完好。
2. 将鼻梁的一面向上，口罩无毛一面为内面，双手撑开口罩带，避免手指接触口罩内面。
3. 将口罩罩于面部，调整至合适位置。
4. 松手后，使其与鼻梁贴合，然后调整鼻夹，使口罩与面部紧密贴合。
【注意事项、警示】
1. 本产品为一次性使用产品，严禁重复使用。使用后应妥善处理。
2. 使用前请检查包装是否完好，包装破损者请勿使用。对外包装标志、生产日期、有效期进行确认，并在有效期内使用。
3. 对无纺布过敏者慎用。

4. 使用过程中如出现呼吸困难等不适情况（呼吸不畅、胸闷、口鼻受污染（如有异物及飞溅等异物）），应及时更换。
【包装】10片/袋，5袋/盒。
【贮存】产品应存放在干燥、通风、避光、防潮、防霉、防虫、防鼠、防污染处。
【保质期】2年

【注册人/生产企业名称】四川新特制药有限公司
【地址】四川省成都市高新西区西芯路12号
【生产地址】四川省成都市高新西区西芯路12号
【联系电话】611731
【联系方式】028-6280555
【网址】http://www.scxya.com
【销售单位】四川新特制药有限公司
【销售电话】028-6280555

产品批号：20200310
生产日期：2020年03月29日
有效期至：2022年2月





日用口罩说明书

口罩主要用于日常防护，在十万级洁净区生产。

- 【产品名称】日用口罩
- 【型号、规格】长方形耳挂式 175mm × 95mm × 3层
- 【结构及组成】本产品由口罩体、鼻梁、口罩带组成。口罩体由无纺布和熔喷无纺布为主要原料热合而成。
- 【适用范围】适用于在日常生活中空气中污染环境过滤除颗粒颗粒物佩戴的口罩。

【使用方法】

1. 打开包装取出口罩，检查口罩是否完好。
2. 有鼻梁的一面向上，口罩无色一面为内侧，双手撑开口罩带，避免手部接触口罩内侧，将口罩置于面部，调整至合适位置。
3. 轻压鼻梁，使其与鼻梁贴合，然后按着鼻夹，将口罩下端调节至下颌处。

【禁忌症、注意事项、警示】

1. 本产品为一次性使用产品，严禁重复使用，使用后应按医院和环保部门要求进行处理。
2. 使用前请检查包装是否完好，包装或口罩破损，请勿使用。对外包装标志、生产日期、有效期进行确认，并在有效期内使用。

3. 对无纺布过敏者慎用。

4. 使用过程中如出现呼吸明显增强（呼吸困难时），口罩破损，口罩受污染（染有血渍及飞沫等异物时），应及时更换。

【包装】10片/袋，5袋/盒。

- 【储运】产品在储运中应能保证密封、不破损、不沾污、不受潮，注意防火、防雨、防酸、防碱、避免强光直射。

【使用期限】2年

【生产日期】见包装。

【产品技术要求编号】Q/SCZY/T-2020-04

【注册人/生产企业名称】四川制药有限公司

【住所】四川省成都市高新西区百叶路18号

【生产地址】四川省成都市高新西区百叶路18号

【邮政编码】61173

【联系方式】028-62808555

【网址】http://www.sczyj.com

【售后服务单位】四川制药有限公司

【咨询电话】028-62808555

【说明书编制日期】2020-03-13



Disposable Mask Instruction Manual

Masks are mainly used for daily protection and are produced in 100,000-level clean areas.

[Product name] Disposable mask

[Model, specifications] rectangular ear-hook type 175mm × 95mm × 3 layers
 [Structure and composition] This product consists of a mask body, a nose clip, and a mask tape. The mask body is made of spunbond non-woven fabric and melt-blown non-woven fabric as the main raw materials.

[Scope of application] It is suitable for wearing masks for filtering out particulate matter under the air pollution environment in daily life.

[Instructions]

1. Open the packaging and take out the mask, and check whether the mask is intact.
2. The side with the nose clip is facing up, the colorless side of the mask is the inside, and the hands are used to support the opening mask to prevent the hands from touching the inside of the mask.
3. Gently press the nose clip to fit the bridge of the nose, then press the nose clip to adjust the lower end of the mask to the lower jaw.

[Contraindications, precautions, warnings]

1. This product is a single-use product, and it is strictly forbidden to reuse it. When finished, it should be disposed of according to the requirements of hospitals and environmental protection departments.

2. Please check whether the packaging is intact before use, and the packaging or mask is damaged, please do not use it. Confirm the external packaging mark, production date and expiration date, and use it within the expiration date.

3. Use with caution for people who are allergic to non-woven fabrics.

4. If there is a significant increase in respiratory resistance during use (when breathing is difficult), the mask is damaged, and the mask is contaminated (when stained with foreign matter such as blood stains and droplets), it should be replaced in time.

[Packing] 10 pieces / pack, 5 bags / box.

[Storage and transportation] During storage and transportation, the product should be sealed, not damaged, not stained, and protected from moisture. Avoid to fire, rain, acid, alkali, and direct sunlight.

[Term of use] 2 years

[Date of production] See the package.

[Product technical requirement number] Q/SCZY/T-2020-04

[Registrant / Manufacturer Name] Sichuan Pharmaceutical, Inc.

[Address] No. 18 Baiye Road, Hi-Tech Zone West Zone, Chengdu City, Sichuan Province.

[Manufacturer Address] No. 18 Baiye Road, Hi-Tech Zone West Zone,

Chengdu City, Sichuan Province.

[Postal code] 611731

[Contact] +86-028-62808555

[Website] http://www.sczyj.com

[After-sales service unit] Sichuan Pharmaceutical, Inc.

[Consultation Tel] +86-028-62808555

[Date of preparation of the manual] 2020-03-13

合格证

Certificate of conformity

四川制药制剂有限公司
SICHUAN PHARMACEUTICAL, INC.

检验员:

Inspectors:

[产品技术要求编号] Q/SICZY 0020-04



本品在十万级洁净车间内生产

产品名称: 日用口罩
 型号规格: 长方形耳挂式 175mm×95mm×3层
 包装规格: 10片/袋×5袋/盒×30盒/箱
 体积: 538mm×495mm×483mm
 储运: 产品在储运中应保证密封、不破损、不沾污、不受潮, 注意防火、防雨、防酸、防碱、避免强光直射。

产品批号:
 生产日期:
 有效期至:

日用口罩

DISPOSABLE MASK

长方形 耳挂式

四川制药有限公司
SICHUAN PHARMACEUTICAL, INC.

地址: 四川省成都市高新西区百叶路18号
电话: 028-62808555

四川制药有限公司
SICHUAN PHARMACEUTICAL, INC.

四川制药口罩对公款账户信息

账户名称：四川制药制剂有限公司

账 号：51001408537051501249

开 户 行：中国建设银行股份有限公司成都高新西区支行

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