名

类

住



统一社会信用代码 91350212MA2Y3Q7DXK 厦门妙杏科技有限公司 法人商享主体 〖有限责任公司(自然人投资或控股)、 厦门市同安区同福路333号四号厂房第五层之一

法定代表人 刘森美 注 册 资 本 壹仟万元整 期 2017年03月24日 业期 限

型

所

成立日

自2017年03月24日至2067年03月23日 商事主体的经营范里、经营场所、投资人信息、年报信息和监管信息等请至厦门市商事主体登记及信用信息公示平台(网址·www.xiamencredit.gov.cn)查询。经营范围中涉及许可审批经营项目的,应在取得有关部门的许可后方可经营。

经 营 范 围

企业信用信息公示系统网址:

2017-3-24 工商登记注册日期 工商登记注册号 依法办理工商登记的企业还须填写以下内容 350821198909093379 刘森美 企业法定代表人姓名 有效证件号

企业资产/个人财产 (折美元) 备注 填表前请认真阅读背面的条款,并由企业法定代表人或个体工商负责人签字、盖章。 2019

Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC. According to 93/42/EEC (MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration number. Face Mask Class I according to Annex IX of 93/42/EEC

> GMDN: 35177 CIBG Number: NL-CA002-2020-50484

NOT AVAILABLE yet Authorized representative name: SUNGO Europe B.V VAT NL857821659B01 ADD: Olympisch stadion 24,1076DE Amsterdam.Netherlands Contact: SUNGO secretary ec.rep@sungogroup.com Basic UDI AND the referred device : not available yet

> CLASS I ,RULE 1 EN 14683:2019

We, the manufacturer , herewith declare under our sole resposibility that the above mentioned products meet the provisions of the regulation (EU)2017/745 on the medical devices (MDR) . ALL

i :EC conformity declaration according to annex II

EU Declaration of conformity

Manufacturer address :5Floor , No.333-4Tongfu Road ,Tongan district ,xiamen ,china P.C 361000

MX-01/175MM*95MM

ACCORIDING TO ANNEX IV of regulation (EU)2017/745 ON MEDICAL DEVICES

Manufacturer: XIAMEN MIAOXING TECHNOLOGY CO.,LTD

Product name: disposable mask

Classification according to MDR:

Confirmity assessment procedure :class

Model /speciification

Standards

+annex III

检测报告

MD medical device Manufacturer Name Address EC REP CE CE Symbol ADJUSTABLE NOSE BRIDGE CLIP

HIGH ELASTIC EARLOOP

Good elastic earloop

No oppression to ears



样品名称 (Sample Description) 委托单位

160920340809

全国服务热线 400-819-5688 北京实验室: (010) 83055000 武汉实验室: (027) 83997127 哈尔滨实验室: (0451)58627755

LTD

2020-04-14~2020-04-22

80

正常 Normal

见下页 See the next page

见下页 See the next page

编制人 (Edited by) 审核人 (Checked by) 批准人 (Approved by) 签发日期 (Issued Date)

公司地址:上海市松江区文翔东路99号7幢2层

测试地址: 上海市松江区文用东路 99 号 5 帧、6 帧、7 帧 1 层、7 帧 3 层 上海市徐江区柱平路 680 号 35 帧 2-4 楼、6 楼

检测结果 (Test Results)

限值

(Limit)

II型

Type II

≥98

<40

≤30

仅对报告照片中的样品负责 Pony authenticate the photo on original report only -以下空白-(End of Report)

谱尼测试集团上海有限公司

Name: disposable Medical Face Mask (non-sterile)

Do not use if the package damaged.

公司地址:上海市松江区文翔东路99号7幢2层

Intend Use: The Face Masks are intended to be worn to protect

测试地址: 上海市松江区文翔东路 99 号 5 幢、6 幢、7 幢 1 层、7 幢 3 层 上海市徐江区柱平路 680 号 35 幢 2-4 楼、6 楼

Instructions for use

both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile. Cautions: 1. Check the package completeness before using. Check the label, manufacturing date and validity time, to make sure the product is in valid date.

IIR 型

Type

IIR

≥98

<60

≥16.0

≤30

谱尼测试集团上海有限公司

尼

3. Do not reuse. Reusing may cause cross-contamination. Instruction for use: 1. Open the packaging pouch and take out the mask. 2. Place the side with nose piece upward. Hang the ear loops on the ears. 3. Press the nose piece to fit the bridge of the nose, then press the nose piece and pull the lower end of the mask to the lower jaw. 4. Adjust the mask so that it covers the bridge of the nose to the lower jaw in order to get the best protection effect. Storage: The product should be stored in a cool (Min 15°C)dry area, away from heat and direct sunlight. Shelf life: 3year Symbols meaning: Symbol Introductions Introductions Do not reuse" are "single #天業 use, "Use only once (2) LOT Batch Code ⚠ Warnings and Precautions non-sterile Manufacture Date Name and Address of EuropeanUnion Representative



THREE-LAYER OF PROTECTION

Adjust size according to face shape

MASK DESIGN







(Applicant) PONY遭 1. 本报告无检验检测专用章、报告赔缝章和批准人签章无效。 This report is invalid without special seal of inspection, cross-page seal and the approver's signatures. 2. 本报告页面所使用"PONY"、"谱尼"字样为本单位的注册商标、其受《中华人民共和国商标法》保护,任何未经本单位校权的擅自使用和仿冒、伪造、变造"PONY"、"谱尼"商标均为违法侵权行为。本单位将依法追究某法律责任。 The pattern and characters of "PONY" and "谱尼" used in this report are protected by the trademark law of the People's Republic of China. Any unauthorized usage, counterfeit, forgery and alteration of trademarks of "PONY" and "譜尼" are the violations of the law. The PONY has the right to pursucall legal liabilities of the subject of the delict. 委託单位对报告数据如有异议,请于报告完成之日起十五日內(初級农产品报告请于报告收到之日起五日內)向本单位书面提出复测申请,同时附上报告原件并预付复测费。 RELEASE TO FIGURE AND THE PROPERTY OF THE PRO

primary agriculture products report).

PONY has not any relevant responsibilities.

8. 本单位有权在完成报告后按规定方式处理所测样品

▲防伪说明(Anti-counterfeiting Description): 报告编号是唯一的;
The test report has exclusive report code

and technique document.

circumstances.

不可重复性或不能进行复测的实验,不进行复测,委托单位放弃异议权利。 Tests that can not be repeated and tested shall not be carried out again.

PONY has the right to dispose the tested sample by rules, after approval of the test report.

苏州实验室: (0512)62997900 太原实验室: (0351) 7555762 No. BOYMAGWR882617L1 样品名称 口罩(非灭菌) facemask (non-sterile) (Sample Description) 厦门妙杏科技有限公司 委托单位 XIAMEN MIAOXING TECHNOLOGY CO., (Applicant) 到样日期 2020-04-14

(Received Date)

检测日期

(Test Date)

样品数量

(Sample Quantity)

样品状态

(Sample Status)

检测项目

(Test Items) 检测方法

(Test Methods) 所用主要仪器

© Hotline 400-819-5688

PONY 谱

www.ponytest.com

No. BOYMAGWR882617L1 样品名称和编号 检测项目 (Sample Description and (Test Items) I型 Number) Type I 细菌过滤效率 (BFE), % ≥95 Bacterial filtration efficiency(BFE) 压力差, Pa/cm² R882617L1 口罩(非灭菌) Differential <40 facemask pressure (non-sterile) 抗溅压力, kPa Splash resistance pressure 物清洁度 cfu/g ≤30 Microbial cleanliness

样品编号和照片 (Sample Number and Photo):

© Hotline 400-819-5688

www.ponytest.com

Aluminum-plastic strip inside Wear firmly, not easy to fall off perfect fit different nose









登记机关 2018年 06月 11日 http://wsgs.fjaic.gov.cn/creditpub 中华人民共和国国家工商行政管理总局监制 医疗器械生产许可证 许可证编号: 闽食药监械生产许20200661号 厦门市同安区同福路333号四号厂房 企业名称: 厦门妙杏科技有限公司 生产地址: 第五层 生产范围: 二类14-14医护人员防护用品*** 法定代表人: 刘森美 企业负责人: 刘森美 所: 厦门市同安区同福路333号四号厂房发证部门: 福建省第品监督管理 31日 2025 年 08 月 30 日 发证日期: 有效期限:至 国家药品监督管理局制 对外贸易经营者 91350212MA2Y3Q7DXK 备案登记表编号: 02910620 进出口企业代码:

厦门市同安区同福路333号四号厂房第五层之一 厦门市同安区同福路333号四号厂房第五层之一 经营场所 (中文) Floor 5, No.4 Plant, No.333 Tongfu Road, Tong'an District, Xiamen City, Fujian PR. China 经营场所 (英文) 13823676951 联系电话 联系传真 1072863948@qq.com 361100 邮政编码 电子邮箱

经营者类型

(由备案登记机关填写)

厦门妙杏科技有限公司

Xiamen Miaoxing Technology Co., Ltd.

私营有限责任公

司

经营者中文名称

经营者英文名称

组织机构代码

住 所

壹仟万元 注册资金 (折美元) 依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容 企业法定代表人/ 有效证件号 个体工商负责人姓名

CE Notification Confirmation This is to confirm that, according to the council directive 93/42/EEC (MDD), SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of: XIAMEN MIAOXING TECHNOLOGY CO., LTD 5Floor, No.333-4tongfu Road, Tongan District, Xiamen, China P.C 36100 The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met. This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated. For and on behalf of . SUNGO Europe B.V. Olympisch Stadion 24, 1076DE Amsterdam, Netherlands Reference Number: EUCAN00200 Issue date: May.06, 2020 SUNGO Europe B.V. Authorized Signature Only used for the EU Representative Signature Olympisch Stadion 24,1076DE

Amsterdam, Netherlands ec.rep@sungogroup.com

2020-04-28, Xiamen , china Signature: XIAMEN MIAOXING TECHNOLOGY COSLTD

Supporting documentations are retained under the premises of the manufacturer .

(Test Report) No. BOYMAGWR882617L1 口罩(非灭菌)facemask(non-sterile) 厦门妙杏科技有限公司 XIAMEN MIAOXING TECHNOLOGY CO., LTD

PONY

Statement

4. 委托单位办理完毕以上手续后,本单位会尽快安排复测。如果复测结果与并议内容相符,本单位将退还委托单位的复测费。 After the applicant finishes the procedure mentioned above, PONY shall arrange the retest as soon as possible. If the retest result accords with the applicant dissent, PONY shall refund the retest fees.

6. 委托单位对样品的代表性和资料的真实性负责,否则本单位不承担任何相关责任。 The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise,

 本报告仅对所测样品负责。报告数据仅及缺对所测样品的评价,对于报告及所裁内容的使用、使用所产生的直接或间接损失及一切法律后果,本单位不承担任何经济和法律责任。 This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.

9. 本单位保证工作的客观公正性,对委托单位的商业信息、技术文件等商业秘密履行保密义务。 PONY assures objectivity and impartiality of the test, and fulfills the obligation of confidentiality for applicant's commercial information,

10. 本报告私自转让、盗用、冒用、涂改、未经本单位批准的复制(全文复制除外)或以其它任何形式的篡改均属无效、本单位将对上运行为严究其相应的法律责任。 The report is invalid in case of illegal transfer, embezzlement, imposture, modification or any altering, reproducing except in full, without approval of PONY, PONY shall investigate and affix the applicant's legal liability accordingly.

(2) 报告采用特制防伪纸张印制,纸张表面带有"PONY"防伪纹路。该防伪纹路不支持复印、即复制件不会带有"PONY"防伪纹路。 The test report is printed by anti-copying paper whose surface shows "PONY" security print with specific anticounterfeiting technique. Security print will disappear after copying. Duplicates are not expected to give "PONY" security print under any

温州实验室: (0577)88271060 上海实验室: (021) 64851999 长春实验室: (0431)85150908 石家庄实验室: (0311)85376660 合肥实验室: (0551)63843474 青岛实验室: (0532)88706866 大连实验室: (0411)87336618 乌鲁木齐实验室: (0991) 6684186 深圳实验室: (0755)26050909 郑州实验室: (0371)69350670 呼和浩特实验室: (0471) 3450025 广州实验室: (020) 89224310 天津实验室: (022) 23607888 西安实验室: (029) 89608785 杭州实验室: (0571)85806807 厦门实验室: (0592)5568048 尼 Testing International Group 结 检 测 (Test Results)

样品规格

(Sample Specification)

商标

(Trade Mark)

生产日期或批号

(Manufacturing Date or

Lot No.)

样品等级

(Sample Grade)

检测类别

(Test Type)

检测环境

(Test Environment)

电热恒温培养箱 Electric Heating Constant Temperature Incubator、

扫描二维码 关注谐尼测试微信 公众号PONY4008195688

第1页, 共2页 (page 1 of 2) 规格 Specification:

17.5×9.5cm

型号 Model: 平面型 Plane

生产日期 Manufacturing

Date: 20200413

生产批号 Manufacturing

Lot No.: 202004

委托检测

(Commissioning Test)

符合要求

(To meet the requirements)

电话: 021-37895599

第2页, 共2页 (page 2 of 2)

检测方法

(Test Methods)

EN 14683: 2019

EN 14683: 2019

EN 14683: 2019

EN 14683: 2019

检测结果

(Test Results)

No.1

No.2

No.3

No.4

No.5

98.9

99.0

98.9

99.1

99.0

36.1

>16.0

24

电话: 021-37895599

(Main Instruments) 细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc 限值标准 Limit Standard: EN 14683: 2019 受检单位 Inspection: 厦门妙杏科技有限公司 XIAMEN MIAOXING TECHNOLOGY CO., LTD 备注 (Note) 以上样品信息由委托单位提供 The information of above sample was provided by the applicant. 2020-04-22

PRECISION WELDING EAR STRAP



