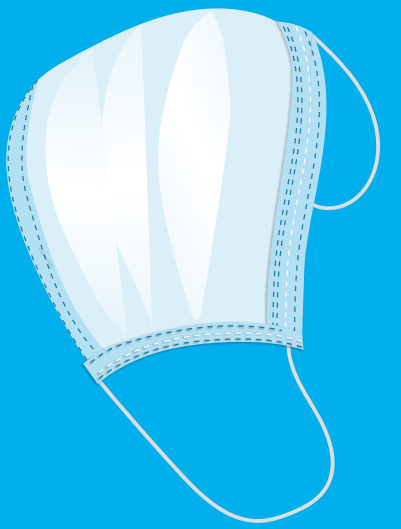
Leading Disposable Medical Face Mask

Professional Medical Device Manufacture

专业医疗器械制造商



公司介绍
COMPANY INTRODUCTION

正合医疗创建于2008年，是国家药监局最高等级三类外科医疗产品的专业设计、生产、营销厂家，产品行销全球50多个国家和地区，企业通过德国TUV严格的体系认证和CE产品认证，以精工品质获得了用户和医疗专家的广泛好评。

我们的目标是为客户提供更简单、更微创、更先进的医疗产品，帮助医学专家解决各种临床难题，使患者减少痛苦和快速恢复健康，享受生活的乐趣。

2020年初新型冠状病毒传播已经逐渐遍布全球，作为中国主流专业医疗器械制造企业之一，我们快速投入到防疫物资的设计、生产中，以专业的知识和卓越的医疗器械生产管理经验快速高效的建立起了日产数百万只一次性医用口罩、一次性外科口罩、民用防护口罩等生产线，并以高水平通过了国内外各类医疗产品注册认证和实验测试。先后获得了国家CFDA医用口罩注册证，欧盟CE认证，澳大利亚TGA认证，并顺利获得商务部白名单资格。

我们本着专业、踏实、负责的态度，愿与全球各地人民携手战胜疫情，回归正常生活。

Established in 2008, Zener Medtec (Changzhou) Co., Ltd. is a Chinese manufacturer dedicated to the research, development, production and marketing of NMPA Class III medical devices. Our products have a marketing history in more 50 countries and regions. Quality management system qulified according to ISO 13485:2016 and products complied to 93/42/EEC with CE marking, Zener has a reputation for its excellent quality from users and experts.

We are aimed to providing more simple, minimally invasive and advanced medical devices to our clients, assist heathcare professionals in sovling clinical problems, minimize patients' pain and speed up their healing progress to restore health and enjoy life again.

Since the beginning of the year 2020, COVID-19 epidemic has spreaded worldwide. As a medical device manufacturer with social responsiblity, we devoted us quickly as thought into the development and production of epidemic prevention products. On the basis of our know-how in the industry and experience in medical device manufacturing management, the prodcution lines of Disposable Medical Face Masks, Disposable Surgical Face Masks and Disposable Protective Face Masks were set up soon, now with a daily production volume of several million pieces. At the same time, regulatory affairs including testing and certification have been drawed more attention. With our medical face mask products registered in CFDA (now NMPA), European Union (CE marking according to 93/42/EEC) and Therapeutic Goods Administration (TGA Australia) , Zener is now on the 'Whilist' of Ministry of Commerce of the People's Republic of China (Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries). Hand in hand, shoulder to shoulder, we're always there for people around the world. We would try our best to help them, conquiring the COVID-19 and being back to tranquility.

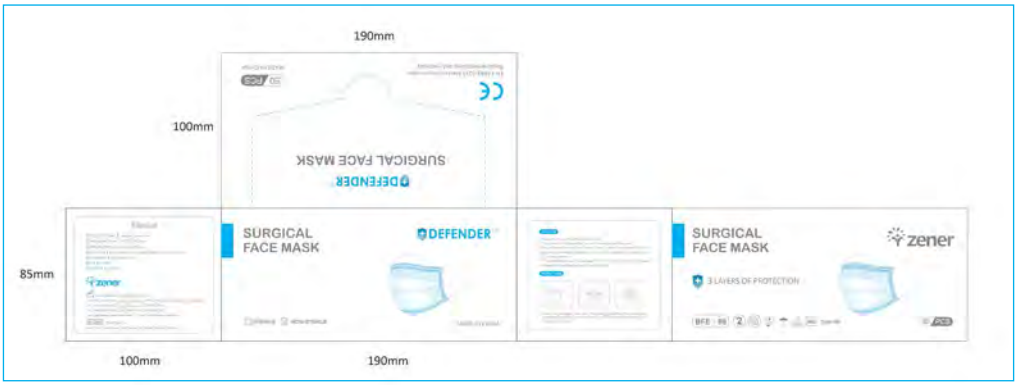
医用口罩
PRODUCTS AND PACKAGING

医用外科口罩

Surgical Face Mask

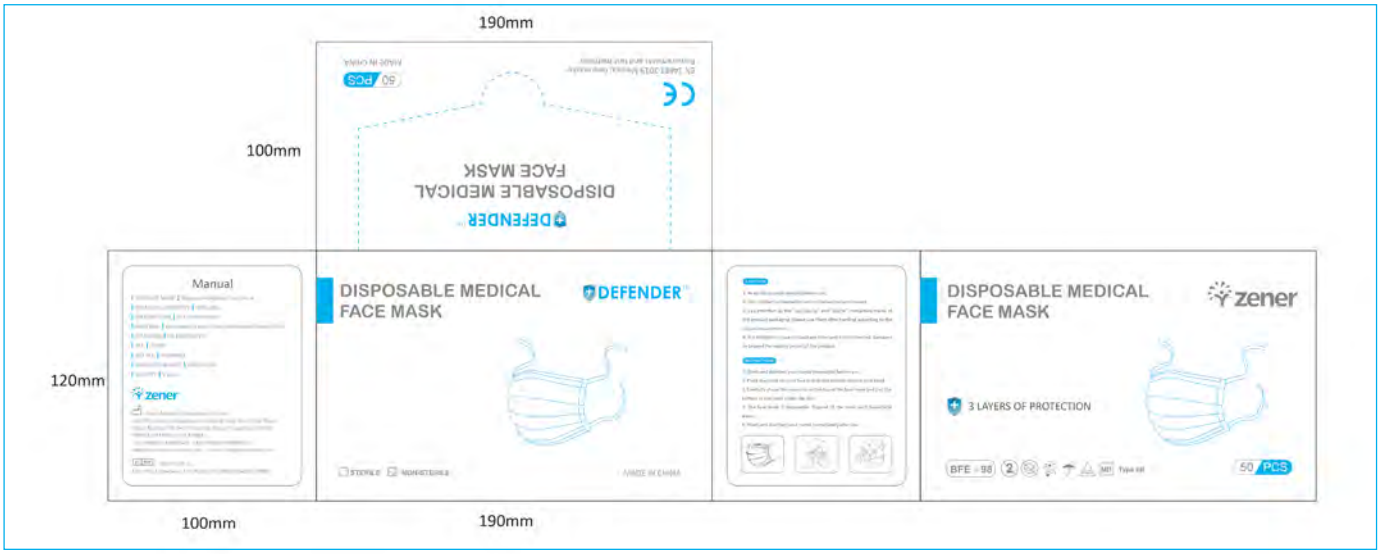
一次性使用医用口罩

Disposable Medical Face Mask



医用口罩
PRODUCTS AND PACKAGING

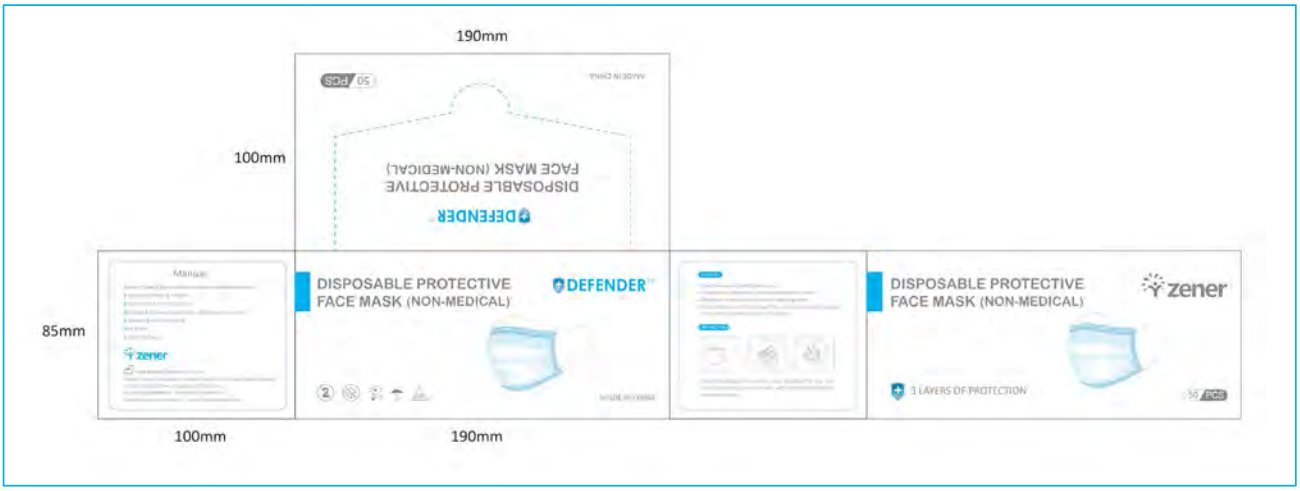
一次性使用医用口罩(绑带式)
Disposable Medical Face Mask(Ties)



防护口罩
PRODUCTS AND PACKAGING

一次性防护口罩(非医用)

Disposable Protective Face Mask
(Non-medical)



KN95口罩
PRODUCTS AND PACKAGING

KN95一次性防护口罩(耳带式)
KN95 Disposable Protective Face Mask
(Earloop Type)

KN95一次性防护口罩(头戴式)
KN95 Disposable Protective Face Mask
(Head-strap Type)

商务部白名单
WHITE LIST FROM CHINA MOFCOM

809	江苏米沙瓦医疗用品有限公司 Jiangsu Mishawa Medical Supplies Co.,Ltd.	91320312663285801N	欧盟CE
810	江阴嘉美针织制衣有限公司 Jiangyin Jiamei Knitting Clothing Co.,Ltd..	91320281726564526N	欧盟CE
811	苏州东山精密制造股份有限公司 Suzhou Dongshan Precision Manufacturing Co., Ltd.	91320500703719732P	欧盟CE
812	泰州永弘医用敷料有限公司 Taizhou Yonghong Surgical Dressing Co.,Ltd	91321200722216479Q	欧盟CE
813	正合医疗科技（常州）有限公司 Zener Medtec (Changzhou) Co.,Ltd.	91320412MA1NELCN8K	欧盟CE
814	江西海州医疗器械有限公司 Jiangxi Haizhou Medical Co.,Ltd.	91360825MA35YB5X42	欧盟CE
815	江西晶康宇医疗科技有限公司 Jiangxi Kinkyu Medical Technology Co., Ltd.	91360728076898355L	欧盟CE
816	江西康蓝医疗器械有限公司 Jiangxi Kanglan Medical Equipment Co., Ltd.	91361023MA394L763T	欧盟CE

Link：

http://www.cccmhpie.org.cn/Pub/6325/176349.shtml

营业执照
BUSINESS LICENSE

编 号 320483666202004100697

统一社会信用代码
91320412MA1NELCN8K (1/1)

营业执照
(副 本)

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 正合医疗科技（常州）有限公司

类 型 有限责任公司

法定代表人 杨盛

经营范围 一类、二类、三类医疗器械的研发、生产、销售；医疗器械技术开发、技术转让、技术咨询、技术服务；生物医药产品、化工新材料的技术转让、技术服务、技术咨询；计算机软件产品开发和销售；化工产品（除危险品）、仪器设备的销售；自营和代理各类商品及技术的进出口业务，国家限定企业经营或禁止进出口的商品和技术除外。日用口罩（非医用）生产；日用口罩（非医用）销售。（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）

注册资本 500万元整

成立日期 2017年02月21日

营业期限 2017年02月21日至••••••

住 所 武进国家高新技术产业开发区西湖路8号津通国际工业园9D栋

登记机关 常州市武进区行政审批局

2020 年 04 月 10 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

医疗器械生产许可证
CFDA MANUFACTURE LICENSE

医疗器械生产许可证

许可证编号：苏药监械生产许应急20200071号

企业名称：正合医疗科技（常州）有限公司

生产地址：江苏省武进高新技术开发区西湖路8号津通国际工业园9D栋1层

法定代表人：杨盛

生产范围：见医疗器械生产产品登记表

企业负责人：杨盛

住　　所：江苏省武进高新技术开发区西湖路8号津通国际工业园9D栋

发证部门：江苏省药品监督管理局

有效期限：至　2021　年　05　月　24　日

发证日期：　2020　年　05　月　25　日

国家食品药品监督管理总局制

医疗器械生产产品登记表

企业名称	正合医疗科技（常州）有限公司
许可证编号	苏有效械生产许20200071号
许可证有效期限	2020-05-25 至 2021-05-24
生产范围	Ⅱ类：14-13-1 手术室感染控制用品，14-14 医护人员防护用品

生产产品列表

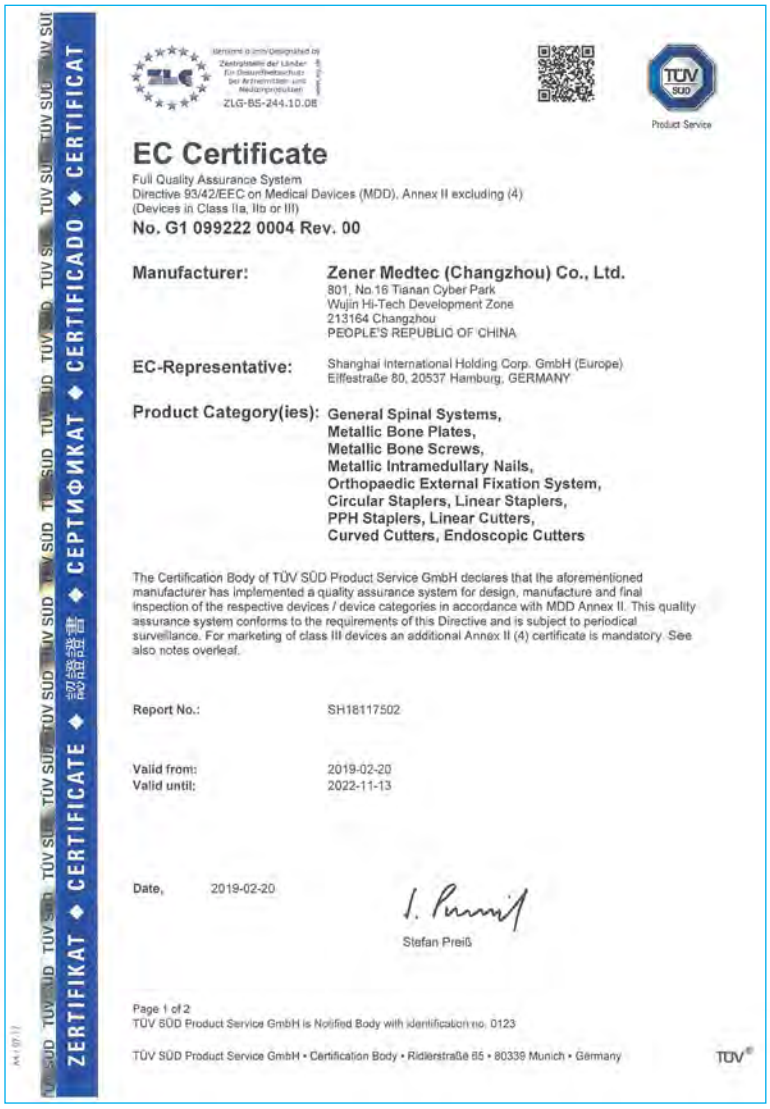
序号	产品名称	注册号	登载日期	备注
1	医用外科口罩	苏械注准20202140158	2020-05-25	有效期至2021-05-19
2	一次性使用医用口罩	苏械注准20202140159	2020-05-25	有效期至2021-05-19

发证部门（公章）：江苏省药品监督管理局

2020年05月25日

第1页/共1页

CE证书
CE CERTIFICATE



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 099222 0004 Rev. 00

Manufacturer: **Zener Medtec (Changzhou) Co., Ltd.**
801, No.16 Tianan Cyber Park
Wujin Hi-Tech Development Zone
213164 Changzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies): **General Spinal Systems,
Metallic Bone Plates,
Metallic Bone Screws,
Metallic Intramedullary Nails,
Orthopaedic External Fixation System,
Circular Staplers, Linear Staplers,
PPH Staplers, Linear Cutters,
Curved Cutters, Endoscopic Cutters**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18117502

Valid from: 2019-02-20
Valid until: 2022-11-13

Date, 2019-02-20

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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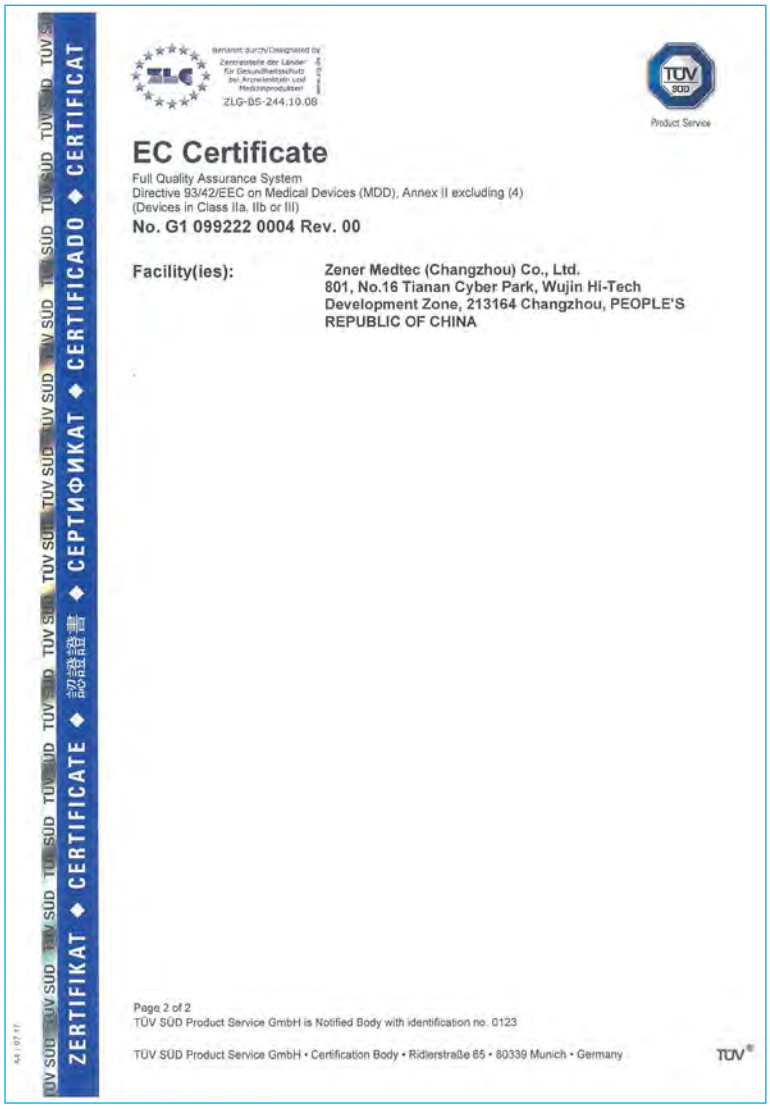
TÜV®



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 099222 0004 Rev. 00

Facility(ies): **Zener Medtec (Changzhou) Co., Ltd.
801, No.16 Tianan Cyber Park, Wujin Hi-Tech
Development Zone, 213164 Changzhou, PEOPLE'S
REPUBLIC OF CHINA**

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ISO 13485证书
ISO 13485 CERTIFICATE

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 099222 0003 Rev. 00

Holder of Certificate: **Zener Medtec (Changzhou) Co., Ltd.**
801, No.16 Tianan Cyber Park
Wujin Hi-Tech Development Zone
213164 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Zener Medtec (Changzhou) Co., Ltd.
801, No.16 Tianan Cyber Park, Wujin Hi-Tech Development Zone,
213164 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of General Spinal Systems, Metallic Bone Plates, Metallic Bone Screws, Metallic Intramedullary Nails, Orthopaedic External Fixation Systems, Circular Staplers, Linear Staplers, PPH Staplers, Linear Cutters, Curved Cutters and Endoscopic Cutters**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18117502

Valid from: 2019-02-15
Valid until: 2020-11-13

Date, 2019-02-15

Stefan Preiß

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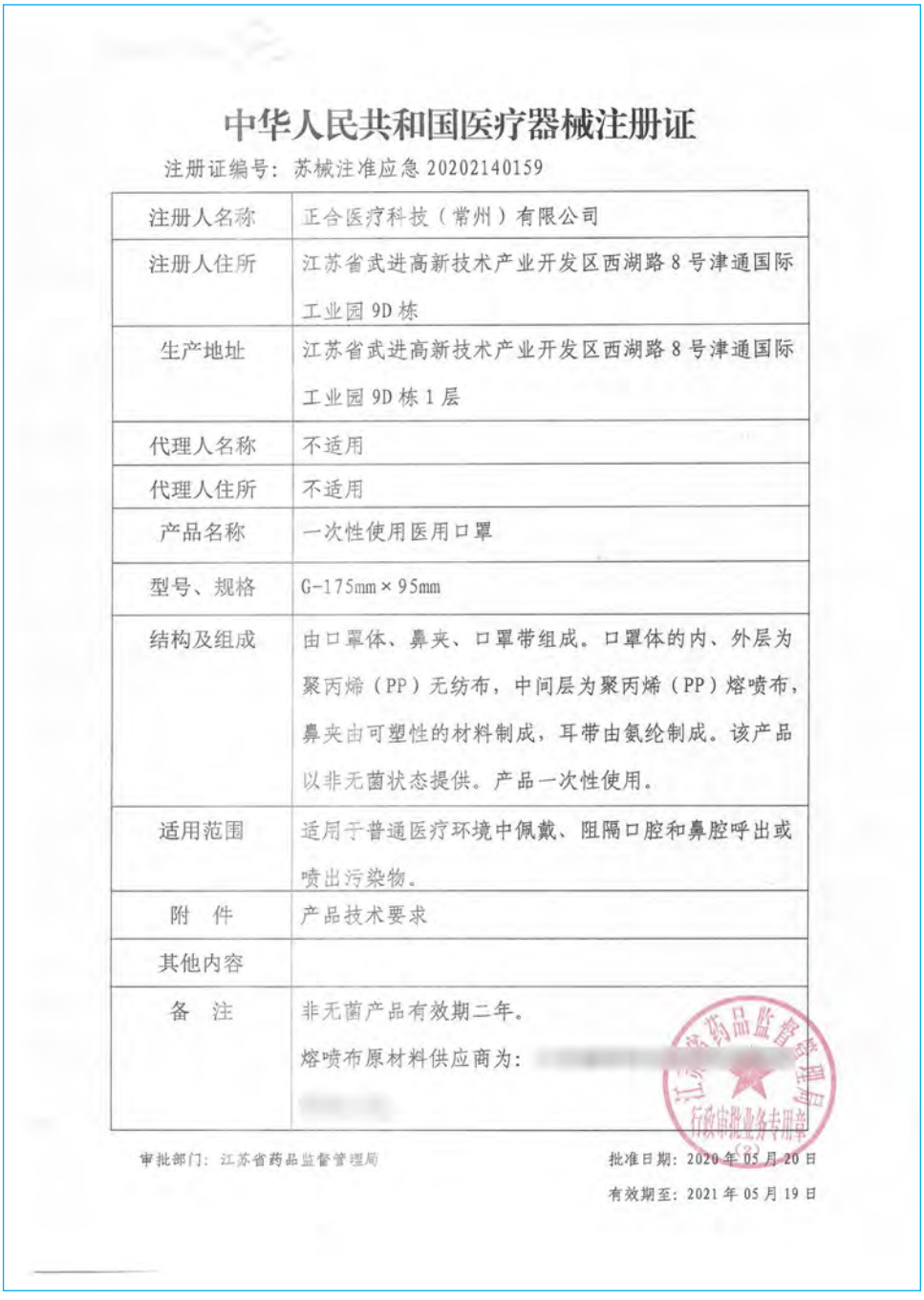
医用口罩注册证
MEDICAL MASK CFDA CERTIFICATE



中华人民共和国医疗器械注册证

注册证编号：苏械注准应急 20202140159

注册人名称	正合医疗科技（常州）有限公司
注册人住所	江苏省武进高新技术产业开发区西湖路 8 号津通国际工业园 9D 栋
生产地址	江苏省武进高新技术产业开发区西湖路 8 号津通国际工业园 9D 栋 1 层
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	G-175mm × 95mm
结构及组成	由口罩体、鼻夹、口罩带组成。口罩体的内、外层为聚丙烯（PP）无纺布，中间层为聚丙烯（PP）熔喷布，鼻夹由可塑性的材料制成，耳带由氨纶制成。该产品以非无菌状态提供。产品一次性使用。
适用范围	适用于普通医疗环境中佩戴、阻隔口腔和鼻腔呼出或喷出污染物。
附　件	产品技术要求
其他内容	
备　注	非无菌产品有效期二年。 熔喷布原材料供应商为：

审批部门：江苏省药品监督管理局　　批准日期：2020 年 05 月 20 日

有效期至：2021 年 05 月 19 日

一次性使用医用口罩 / Disposable Medical Face Mask

注册检验报告
CFDA TEST REPORT

检 验 报 告

Test Report

（2020 ）ZC 类第 0654 号

样品名称 Product Name：一次性使用医用口罩

规格型号 Specifications：G-175mm×95mm

检验类别 Test Category：注册检验

委托单位 Entrusting Unit：正合医疗科技（常州）有限公司

江苏省医疗器械检验所
Jiangsu Testing and Inspection Institute for Medical Devices

江苏省医疗器械检验所
检验报告首页

报告编号：2020ZC0654　　首页1页 W1页 S1页 Z1页 共4页

样品名称	一次性使用医用口罩 送样（√） 抽样（）	样品编号	SLZC2003325
商标	/	规格型号	G-175mm×95mm
委托方	正合医疗科技（常州）有限公司	检验类别	注册检验
委托方通讯地址	江苏省武进高新技术产业开发区西湖路8号津通国际工业园9D	产品编号/批号	F03BY001
标示生产单位	正合医疗科技（常州）有限公司	抽样单编号	/
受检单位	正合医疗科技（常州）有限公司	生产日期	2020.03.04
抽样单位	/	样品数量	215只
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	本检验所试验室
收样日期	2020年3月31日	检验日期	2020年4月13日-2020年5月15日
检验项目	全项目		
检验依据	正合医疗科技（常州）有限公司产品技术要求《一次性使用医用口罩》		
检验结论	被检样品符合正合医疗科技（常州）有限公司产品技术要求《一次性使用医用口罩》规定的要求。 （检验报告专用章或检验单位公章） 签发日期：2020年5月15日		
备注	1）报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2）报告页眉中的“W”表示物理，“S”表示生物，“Z”表示原件。 3）熔喷布原材料单位名称：江苏盛纺纳米材料科技股份有限公司。		

批准：

职务：

一次性使用医用口罩 / Disposable Medical Face Mask

医用外科口罩注册证
SURGICAL MASK CFDA CERTIFICATE

中华人民共和国医疗器械注册证

注册证编号：苏械注准应急 20202140158

注册人名称	正合医疗科技（常州）有限公司
注册人住所	江苏省武进高新技术产业开发区西湖路 8 号津通国际工业园 9D 栋
生产地址	江苏省武进高新技术产业开发区西湖路 8 号津通国际工业园 9D 栋 1 层
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩
型号、规格	W-17.5cm × 9.5cm
结构及组成	由口罩体、鼻夹、口罩带组成。口罩体的内、外层为聚丙烯（PP）无纺布，中间层为聚丙烯（PP）熔喷布，鼻夹由可塑性的材料制成，耳带由氨纶制成。该产品以非无菌状态提供。产品一次性使用。
适用范围	适用于临床医务人员在有创操作等过程中佩戴。
附　件	产品技术要求
其他内容	
备　注	非无菌产品有效期二年。 熔喷布原材料供应商为：[redacted]

审批部门：江苏省药品监督管理局

批准日期：2020 年 05 月 20 日

有效期至：2021 年 05 月 19 日

医用外科口罩 / Surgical Face Mask

注册检验报告
CFDA TEST REPORT

检 验 报 告

Test Report

（2020 ）ZC 类第0653 号

样品名称 Product Name：医用外科口罩

规格型号 Specifications：W-17.5cm×9.5cm

检验类别 Test Category：注册检验

委托单位 Entrusting Unit：正合医疗科技（常州）有限公司

江苏省医疗器械检验所
Jiangsu Testing and Inspection Institute for Medical Devices

江苏省医疗器械检验所
检验报告首页

报告编号：2020ZC0653　　首页1页 W2页 S1页 Z1页 共5页

样品名称	医用外科口罩 送样（√） 抽样（）	样品编号	SL2C2003326
商标	/	规格型号	W-17.5cm×9.5cm
委托方	正合医疗科技（常州）有限公司	检验类别	注册检验
委托方通讯地址	江苏省武进高新技术产业开发区西湖路8号津通国际工业园9D	产品编号/批号	F04BY001
标示生产单位	正合医疗科技（常州）有限公司	抽样单编号	/
受检单位	正合医疗科技（常州）有限公司	生产日期	2020.03.04
抽样单位	/	样品数量	215只
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	本检验所试验室
收样日期	2020年3月31日	检验日期	2020年4月10日-2020年5月15日
检验项目	全项目		
检验依据	正合医疗科技（常州）有限公司产品技术要求《医用外科口罩》		
检验结论	被检样品符合正合医疗科技（常州）有限公司产品技术要求《医用外科口罩》规定的要求。（检验报告专用章或检验单位公章）签发日期 2020年5月15日		
备注	1）报告中的“——”表示此项不适用，报告中“/”表示此项空白。 2）报告页眉中的“W”表示物理，“S”表示生物，“Z”表示照片。 3）熔喷布原材料单位名称：江苏盛纺纳米材料科技股份有限公司。		

批准：

职务：

医用外科口罩 / Surgical Face Mask

KN95检验检测报告
KN95 (GB 2626-2006) TEST REPORT

171021110579

检验检测报告

TEST REPORT

STFWT20208815

产品名称 Product Name	口罩
委托单位 Trust Unit	正合医疗科技（常州）有限公司
生产单位 Manufacturer	正合医疗科技（常州）有限公司
检验检测类别 Test Category	委托送样检验

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

STFWT20208815

共 5 页 第 1 页
Page 1 of 5

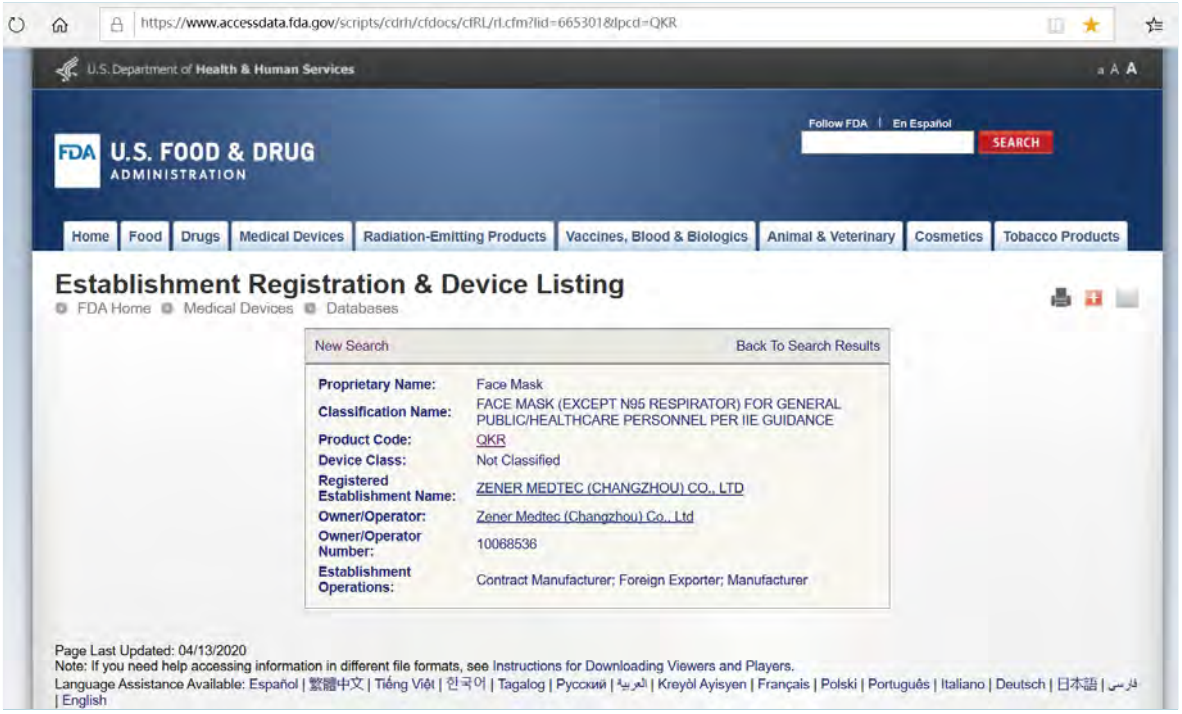
产品名称 Product Name	口罩	规格型号 Specification Type	KN95
		商 标 Trademark	——
委托单位 Trust Unit	正合医疗科技（常州）有限公司	电 话 Tel	13861287103
生产单位 Manufacturer	正合医疗科技（常州）有限公司	样品等级 Sample Grade	——
样品数量 Sample Quantity	40 只	送样日期 Sample Receiving Date	2020-04-10
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	FDSBY001
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 2626-2006《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的 KN95 级要求。 签发日期：2020-04-24 SignatuimDate		
备 注 Remarks	标记“——”的检测项目表示不予单项评价或不具备单项评价条件。 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。		

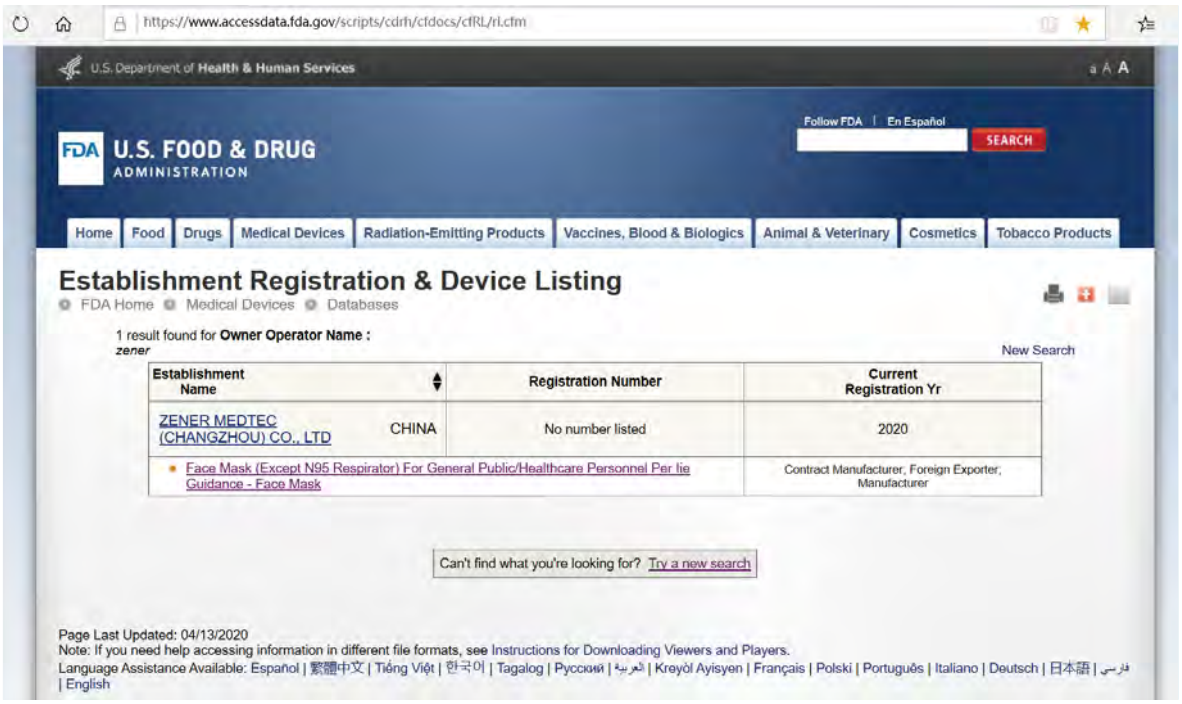
批 准： Approver　　审 核： Examiner　　主 检： Majortester

KN95防护口罩 / KN95 Disposable Protective Face Mask

GB 2626-2006

FDA工厂注册&器械列示
FDA ESTABLISHMENT REGISTRATION & DEVICE LISTING





CE符合性声明
CE DECLARATION OF CONFORMITY

Declaration of Conformity

Manufacturer:	**Zener Medtec (Changzhou) Co., Ltd.** 9D, Jinton International Industrial Park, No. 8 Xihu Road, Wujin National Hi-Tech Industrial Zone, Changzhou 213164, PEOPLE'S REPUBLIC OF CHINA
European Representative:	**ZOUSTECH S.L.** Pso. Castellana,141–Planta 19, 28046–Madrid, SPAIN
Product Name	Disposable Medical Face Mask
Model Number:	G-175mm×95mm, G-145mm×95mm, W-17.5cm×9.5cm, W-14.5cm×9.5cm
UMDNS-Code:	12447

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47

Signature: Yang Sheng

Name: Yang Sheng

Place& Date: Changzhou, 2020-05-19

Position: Management Representative

CE欧代声明
CE PRODUCT NOTIFICATIONS

ZOUSTECH

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Zoustech, your trusted partner
Representing you in EU!

CONFIRMATION OF PRODUCT NOTIFICATION

This is to confirm that Zoustech S.L., has registered under the AEMPS (Spanish Agency for Medicines and Medical Devices), the following medical devices:

Number in the contract	Product name in English	Product name in Spanish
1	Disposable Medical Face Mask	Mascarilla facial médica desechable

Manufacturer: ZENER MEDTEC (CHANGZHOU) CO., LTD.

Address: 9D, Jinton International Industrial Park, No. 8 Xihu Road, Wujin National Hi-Tech Industrial Zone, 213164 Changzhou, PEOPLE'S REPUBLIC OF CHINA

Registered under number: RPS/895/2020 (See attached the electronic notification)

The Manufacturer has declared that these devices comply with the regulation including all the general safety and performance requirements.

Zoustech has complied with its commitment of registering the above mentioned devices under the AEMPS and will not have any other further obligation, compromise or responsibility.

19 May, 2020

Zoustech S.L.
Pso. Castellana, 141 - Pl. 19
28046 Madrid
Spain

Mr. Rubén Valle Ibaseta
On behal of
ZOUSTECH SL

西班牙食药监局注册备案
AEMPS REGISTRATION

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD · agencia española de medicamentos y productos sanitarios

Envíos Telemáticos 3.0.44

Registro de Responsables de Productos Sanitarios

Usuario: RUBÉN VALLE IBASETA Desconectar

Registro de Responsables de Productos Sanitarios - RPS/895/2020

Datos de la notificación

Datos de registro

Nº Registro	RPS/895/2020	Fecha Registro	19/05/2020

Datos del Responsable

Tipo de Responsable (*)	Rep. Autorizado	Tipo de entidad	Empresa
CIF(*)	B87637591	Nombre (*)	ZOUSTECH S.L
Dirección(*)	Paseo de la castellana 141 Planta 19		
Localidad (*)	Madrid		
Provincia(*)	Madrid	CP(*)	28046
Teléfono(*)	694 426 446	Fax	
e-mail(*)	legal@zoustech.eu	Web	

Datos del Fabricante

Nombre o Razón Social (*)	Zener Medtec (Changzhou) Co., Ltd		
Dirección (*)	9D, Jinton International Industrial Park, No. 8 Xihu Road, Wujin National Hi-Tec		
Localidad (*)	Industrial Zone, Changzhou		
País(*)	República Popular China	CP	213164
Teléfono (*)	008651983800520	Fax	
e-mail (*)	zh@zenermed.com	Web	

Datos de Productos Comunicados

Estatus(*) Primera Comunicación

Relación de Productos

Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios

Nombre Comercial	Tipo de Producto	Estado del producto	Acción
MASCARILLA FACIAL MÉDICA DESECHABLE	Clase I	Primera Comunicación	

Comentarios

Enviar Solicitud

Agencia Española de Medicamentos y Productos Sanitarios
Parque Empresarial "Las Mercedes", Edif. 8, C/ Campezo 1 - 28022 MADRID | e-Mail: incidencias_aplicaciones@aemps.es

EN 14683检测报告
EN 14683 TEST REPORT

SGS

ilac-MRA CNAS

中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025246178301TX** **Date:May 14,2020** **Page 1 of 3**

ZENER MEDTEC(CHANGZHOU)CO., LTD.
9D, JINTON INTERNATIONAL INDUSTRIAL PARK, NO.8 XIHU ROAD, WUJIN NATIONAL HI-TECH INDUSTRIAL ZONE, CHANGZHOU 213164, PEOPLE'S REPUBLIC OF CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable medical face mask
Style No.	:	G-175mmX95mm
Composition	:	(A)Non-woven fabric/ meltblown fabric
Sample Color	:	(A)Blue
Manufacturer	:	ZENER MEDTEC(CHANGZHOU)CO., LTD.
Supplier	:	ZENER MEDTEC(CHANGZHOU)CO., LTD.
Proposed Care Instruction	:	/
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Apr 28, 2020
Testing Period	:	Apr 28, 2020 - May 14, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

3rd Building,No.889,Yishan Road,Xuhui District,Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e sgs.china@sgs.com

澳大利亚药品管理局注册证
AUSTRALIA TGA CERTIFICATE

Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Perios Pty Ltd

for approval to supply

Perios Pty Ltd - Mask, <specify>

ARTG Identifier	336210
ARTG Start Date	12/05/2020
Product Category	Medical Device Included Class 1
GMDN	12447
GMDN Term	Mask, <specify>
Intended Purpose	Disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms.

Manufacturer Details	Address	Certificate number(s)
Zener Medtec (Changzhou) Co Ltd	9D Jinton International Industrial Park No 8 Xihu Road Wujin National Hi Tech Industrial Zone , Changzhou , 213164 China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Mask, <specify>

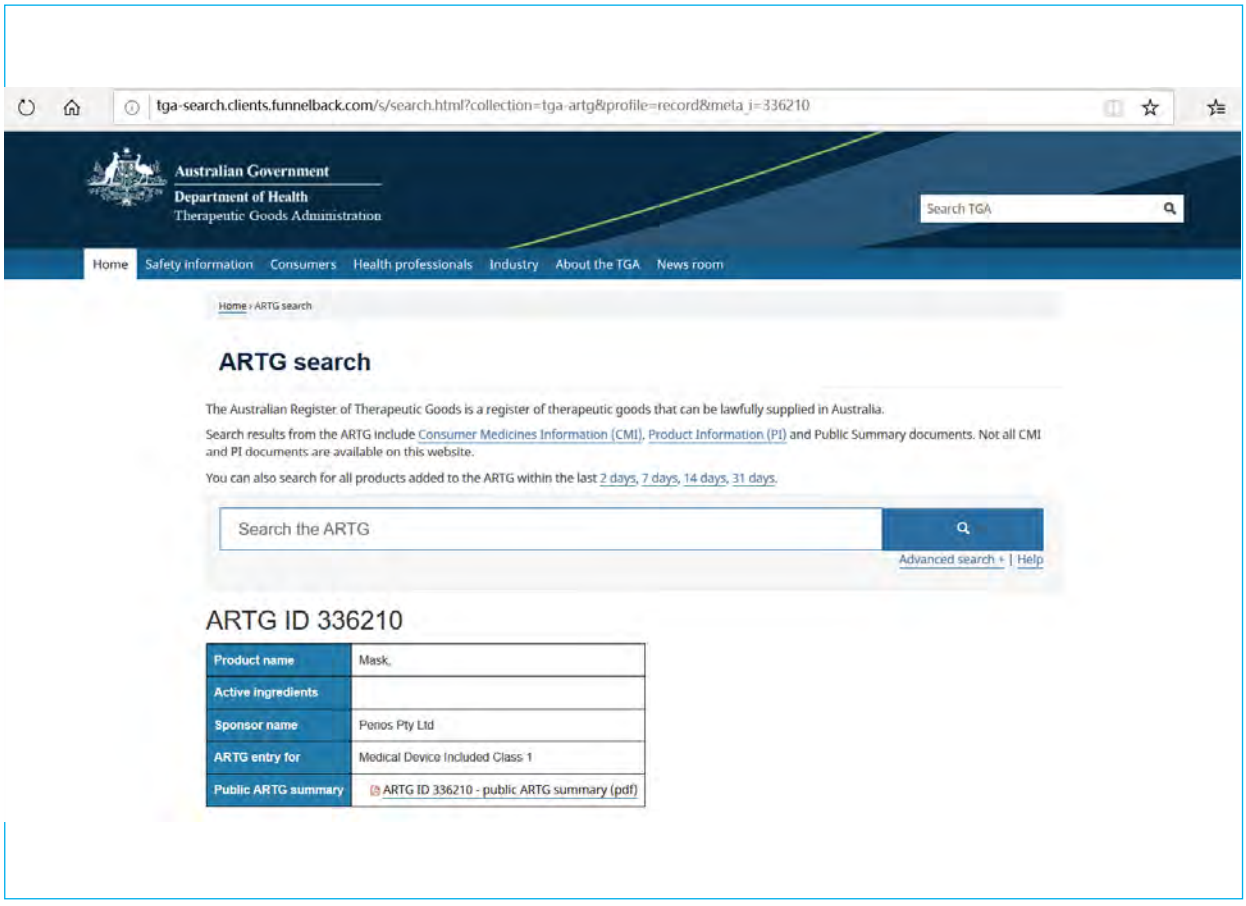
Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 336210
ARTG Start Date: 12/05/2020

澳大利亚药品管理局注册证
AUSTRALIA TGA CERTIFICATE



tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=336210

Australian Government
Department of Health
Therapeutic Goods Administration

Search TGA

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Home › ARTG search

ARTG search

The Australian Register of Therapeutic Goods is a register of therapeutic goods that can be lawfully supplied in Australia.

Search results from the ARTG include Consumer Medicines Information (CMI), Product Information (PI) and Public Summary documents. Not all CMI and PI documents are available on this website.

You can also search for all products added to the ARTG within the last 2 days, 7 days, 14 days, 31 days.

Search the ARTG

Advanced search › | Help

ARTG ID 336210

Product name	Mask,
Active ingredients	
Sponsor name	Penos Pty Ltd
ARTG entry for	Medical Device Included Class 1
Public ARTG summary	ARTG ID 336210 - public ARTG summary (pdf)

澳大利亚药品管理局注册证
AUSTRALIA TGA CERTIFICATE

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 336210 Perios Pty Ltd - Mask, <specify>

ARTG entry for	Medical Device Included Class 1
Sponsor	Perios Pty Ltd
Postal Address	55 Murray St, Wilston, QLD, 4051 Australia
ARTG Start Date	12/05/2020
Product Category	Medical Device Class 1
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Zener Medtec (Changzhou) Co Ltd	9D Jinton International Industrial Park No 8 Xihu Road Wujin National Hi Tech Industrial Zone, Changzhou, 213164 China

Products

1 . Mask, <specify>

Product Type	Single Device Product	**Effective Date**	12/05/2020
GMDN	12447 Mask, <specify>		
Intended Purpose	Disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

This is not an ARTG Certificate document.

The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

生产车间
PRODUCTION ENVIRONMENT








ZENER MEDTEC (CHANGZHOU) CO.,LTD
Add: Bldg 9D, Jinton International Industrial Park, No. 8 Xihu Road, Wujin Hi-Tech Industry Zone,Changzhou , China. 213164
Tel: +86 0519-83800520
E-mail: info@zenermed.com
www.zenermed.com

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