江苏兴通生物科技集团有限公司

外

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一、生产许可证

医疗器械生产许可证

许可证编号：苏食药监械生产许20090052号

企业名称：江苏兴通生物科技集团有限公司

生产地址：扬州市广陵北洲工业园头桥片区客乐路8号

法定代表人：刘维春

生产范围：见医疗器械生产产品登记表

企业负责人：张卫方

住　　所：扬州市广陵北洲工业园头桥片区客乐路8号

发证部门：江苏省药品监督管理局

有效期限：至　2024　年　04　月　15　日

发证日期：　2019　年　04　月　16　日

国家食品药品监督管理总局制

二、营业执照

编号 32100000020200318010 3

统一社会信用代码

91321000798629851M (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 江苏兴通生物科技集团有限公司

类型 有限责任公司(自然人独资)

法定代表人 刘维春

经营范围 生物制品技术研发，塑料制品手工组装，纸张、纸胶片及相关电子设备、电子产品销售；一、二、三类医疗器械的生产、销售；自动输液器设备组装、销售。消毒剂生产（不含危险化学品）；消毒剂销售（不含危险化学品）；劳动保护用品生产；劳动保护用品销售；医用口罩生产；医用口罩零售；医用口罩批发；日用口罩（非医用）生产；日用口罩（非医用）销售；医护人员防护用品零售；医护人员防护用品批发；货物进出口；技术进出口；进出口代理（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 10000万元整

成立日期 2007年02月27日

营业期限 2007年02月27日至******

住所 扬州市广陵北洲工业园头桥片区客乐路8号

登记机关 扬州市市场监督管理局

2020 年 03 月 18 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

三、对外贸易经营者备案登记表

对外贸易经营者备案登记表

备案登记表编号：04215803　　统一社会信用代码：91321000798629851M

进出口企业代码：

经营者中文名称	江苏兴通生物科技集团有限公司		
经营者英文名称	Jiangsu Xingtong Biotechnology Group Co., Ltd.		
组织机构代码	————	经营者类型（由备案登记机关填写）	私营有限责任公司
住　所	扬州市广陵北洲工业园头桥片区客乐路8号		
经营场所（中文）	扬州市广陵北洲工业园头桥片区客乐路8号		
经营场所（英文）	No.8,Kele road，Touqiao Area，Beizhou Industrial Park，Guangling Zone ,Yangzhou City,China		
联系电话	0514-87485222	联系传真	0514-87481010
邮政编码	225000	电子邮箱	410540732@qq.com
工商登记注册日期	2009-2-27	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

企业法定代表人姓名	刘维春	有效证件号	321027196803025117
注册资金	壹亿元	（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/个体工商负责人姓名		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。

备案登记机关

签　章

2020 年 03 月 16 日

四、海关进出口货物收发货人备案回执

海关进出口货物收发货人备案回执

企业名称	江苏兴通生物科技集团有限公司
统一社会信用代码	91321000798629851M
海关备案日期	2020-03-17
海关编码	3210962267
检验检疫备案号	3267300148
有效期	长期

扬州海关

2020 年 3 月 17 日

自然人、法人或者非法人组织可通过"中国海关企业进出口信用信息公示平台"（http://credit.customs.gov.cn）或者"互联网+海关"（http://online.customs.gov.cn）查询海关公示的企业信息。

五、汇款资料

The Agricultural Bank of China,Jiangsu ,Yangzhou ,Guangling Sub-Branch

please request the remitter to instruct their bank to use the following payment routing information.

中国农业银行股份有限公司扬州广陵支行美元汇款线路：

INTERMDIARY BANK（中间行）：（仅供参考）

JPMORGAN CHASE BANK

NEW YORK

摩 根 大 通 银 行 纽 约 分 行

SWIFT BIC（代码）：CHASUS33

BENEFICIARY BANK（收款行）：

The Agricultural Bank of China , Jiangsu Branch

中 国 农 业 银 行 江 苏 省 分 行

SWIFT BIC（代码）:ABOCCNBJ100

BENEFICIARY(收款人)：

NAME(名称)： JIANGSU XINGTONG BIOTECHNOLOGY GROUP CO.,LTD

ACCOUNT NUMBER（帐号）： 10158314040005451

ADD: NO.8 KELE ROAD,TOUQIAO TOWN

CITY, PROVINCE: YANGZHOU CITY,JIANGSU PRO., CHINA

Thank you for banking with
The Agricultural Bank of China,Jiangsu,Yangzhou,Guangling Branch

六、CIBG 荷兰注册

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ ZERTIFIKAT ◆ CERTIFICATE

Sungo global service

CERTIFICATE OF NOTIFICATION

This is to certify that, according to the council regulation 2017/745/EU, SUNGO Europe B.V. performed all notification duties and responsibilities as the European authorized representative of:

Applicant:	Jiangsu Xingtong Biotechnology Group Co., Ltd.
Address:	No.8, Kele road，Touqiao Area，Beizhou Industrial Park，Guangling Zone, Yangzhou City, China

The Manufacturer has provided SUNGO Europe B.V. with all the appropriate declarations according to the 2017/745/EU Regulation requirements including the EC Declaration of Conformity confirming that his medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Regulation 2017/745/EU.

Product(s):	Medical face mask
Type(s):	large, medium, small and extra small
Product Classification:	Class I

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

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

SUNGO Executive Director Sungo global service CERTIFIED

Issued: Mar. 20 2020

Cert. No.: EU205518

Expiration Date: Mar. 19 2025

CE

*This is not a CE mark and is only provided as a template for informational

SUNGO CONTACT INFORMATION
Email: info@sungoglobal.com Website: www.sungoglobal.com

七、荷兰注册信函

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20200567

Bijlagen
-

Uw aanvraag
10 maart 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 16 maart 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 10 maart 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Jiangsu Xingtong Biotechnology Group Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

MEDICAL FACE MASK
(geen merknaam) (NL-CA002-2020-49530)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

zer niet gedefinieerd.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dhr. M.J. van de Velde

八、FDA 注册

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

JIANGSU XINGTONG BIOTECHNOLOGY GROUP CO., LTD.
No.8,Kele road,Touqiao Area,Beizhou Industrial Park,Guangling Zone Yangzhou, Jiangsu, 225109, CHINA
has completed the FDA Establishment Registration (as manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Owner/Operator Number: 10063124
Device Listing#:

Listing No	Code	Device Name
D375381	LYU	ACCESSORY, SURGICAL APPAREL (Medical Face Mask)

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. 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. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

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. SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Sungo global service FDA

Executive Director
Issued: Mar. 18 2020
Cert. No.: 2007US086518
Expiration Date: Dec. 31 2020

DRAFT

九、Use Instructions（使用说明）

Instructions for use

Name: Medical Face Mask

Intend Use: The Face Masks are intended to be worn to protect 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.
2. Do not use if the package damaged.
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 Normal atmospheric temperature, away from heat and direct sunlight.

Shelf life: 3 years

十、产品图片

内盒尺寸：190mm*100mm*90mm

大箱重量：9.0Kg　　大箱尺寸：52cm*39cm*39.5cm