EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60135422 0001

Report No.: 15083140 006

Manufacturer:
Xiantao Tongda Non-woven
Products Co., Ltd.
No. 28, Pengchang Road
433018 Xiantao
China

Products:
Aspects of manufacture concerned with securing and maintaining sterile conditions:
Face Masks, Surgical Gowns, Coveralls, Caps

Replaces Approval, Registration No.: DD 60102531 0001

Expiry Date: 2024-01-16

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-07-16

Date: 2019-07-16

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

中华人民共和国医疗器械注册证

注册证编号：鄂械注准20202142956

注册人名称	仙桃市通达无纺布制品有限公司
注册人住所	仙桃市彭场镇仙沙公路南侧
生产地址	仙桃市彭场镇禾丰村胡家路南侧
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	平面耳挂式(长×宽）：175*95mm 非灭菌级。
结构及组成	口罩由两层聚丙烯纺粘无纺布夹一层聚丙烯熔喷布经折叠超声波复合而成。口罩上配有鼻夹及口罩带，鼻夹由可塑性材料聚丙烯镀锌铁线制成；口罩带为耳挂式，由涤纶和氨纶材料制成。
适用范围	供临床各类人员在非有创操作过程中佩带，覆盖住使用者的口、鼻及下颌，为防止病原体微生物、颗粒物的直接透过提供一定的物理屏障。
附　件	产品技术要求。
其他内容	无
备　注	医疗器械注册证有效期1年。

审批部门：湖北省药品监督管理局

批准日期：2020 年 5 月 9 日

有效期至：2021 年 5 月 8 日

（审批部门盖章）

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

Xiantao Tongda Non-Woven Products Co., Ltd.
South Of Xiansha Road, Pengchang Town, Xiantao, Hubei, 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

Registration Number:3011511692
Device Listing#: See annex

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: Dec. 23 2019
Cert. No.: 2006US464538
Expiration Date: Dec. 31 2020

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

Annex to Cert. No.: 2006US464538

Listing No	Code	Device Name
D306060	FXP	COVER, SHOE, OPERATING-ROOM (Boot Cover; Disposable Slipper; Shoe Cover; Sleeve Cover)
D306061	FOG	HOOD, OXYGEN, INFANT (Diposable Hood)
D306062	FYF	CAP, SURGICAL (Cap/Disposable Cap/Surgical Cap/Non Woven Cap; Nurse Cap; Worker Cap; Doctor Cap)
D306063	KME	BEDDING, DISPOSABLE, MEDICAL (Disposable Bed Sheet; Disposable Pillow Cover)
D306064	LYU	ACCESSORY, SURGICAL APPAREL (Beard Cover)
D306065	FME	GOWN, EXAMINATION (Patient Gown)
D306066	IWO	APRON, PROTECTIVE (Apron)
D306067	FXO	SUIT, SURGICAL (Coverall)
D306068	OEA	NON-SURGICAL ISOLATION GOWN (Cpe Gown; Isolation Gown; Pe Rain Coat)
D306069	FYE	DRESS, SURGICAL (DRESSING/Visitor Gown/Clothing; Visitor Gown; Surgical Gown)
D306070	BWP	SHOE AND SHOE COVER, CONDUCTIVE (Shoe Cover)
D307072	KHA	MASK,SCAVENGING (Face Mask)

END OF THE ANNEX

SUNGO CHINA OFFICE Tel: 021-68828052 Email:Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

PONY 谱尼测试
Pony Testing International Group

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160920340809

检 测 报 告
(Test Report)

No. BOYBXQSR817757L1

样品名称 (Sample Description)	一次性医用口罩 Disposable Medical Face Mask
委托单位 (Applicant)	仙桃市通达无纺布制品有限公司 Xiantao Tongda Non-woven Products Co.,Ltd.

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声 明
Statement

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If the applicant has any questions about the results, shall provide a written retest application with the original report, and prepay the retest fees to PONY within fifteen days since the approval date (as an exception, it shall be within five days since the date received for the primary agriculture products report).

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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.

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上海实验室: (021) 64851999　长春实验室: (0431)85150908　石家庄实验室: (0311)85376660　温州实验室: (0577)88271060
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PONY 谱尼测试
Pony Testing International Group

检测结果
(Test Results)

No. BOYBXQSR817757L1

样品名称 (Sample Description)	一次性医用口罩 Disposable Medical Face Mask	样品规格 (Sample Specification)	——
委托单位 (Applicant)	仙桃市通达无纺布制品有限公司 Xiantao Tongda Non-woven Products Co.,Ltd.	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-03-25	生产日期或批号 (Manufacturing Date or Lot No.)	——
检测日期 (Test Date)	2020-03-25~2020-04-08	样品等级 (Sample Grade)	——
样品数量 (Sample Quantity)	50 只 50Pcs	检测类别 (Test Type)	委托检测 (Commissioning Test)
样品状态 (Sample Status)	全新 50 只，包装完好，3 层无纺布，熔喷布过滤，耳挂 New 50 pcs, packed in good condition, 3 layers of non-woven cloth, fusible spray cloth filter, ear hanging	检测环境 (Test Environment)	符合要求 (To meet the requirements)
检测项目 (Test Items)	见下页 See the next page		
检测方法 (Test Methods)	见下页 See the next page		
所用主要仪器 (Main Instruments)	恒温培养箱 Constant Temperature Incubator、 细菌过滤效率检测仪 Bacterial filtration efficiency detector 等 etc		
备注 (Note)	限值标准 Limit on：EN 14683：2019		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)		
	审核人 (Checked by)	郭惠	
	批准人 (Approved by)		
	签发日期 (Issued Date)	2020-04-08	

✆ Hotline 400-819-5688
www.ponytest.com

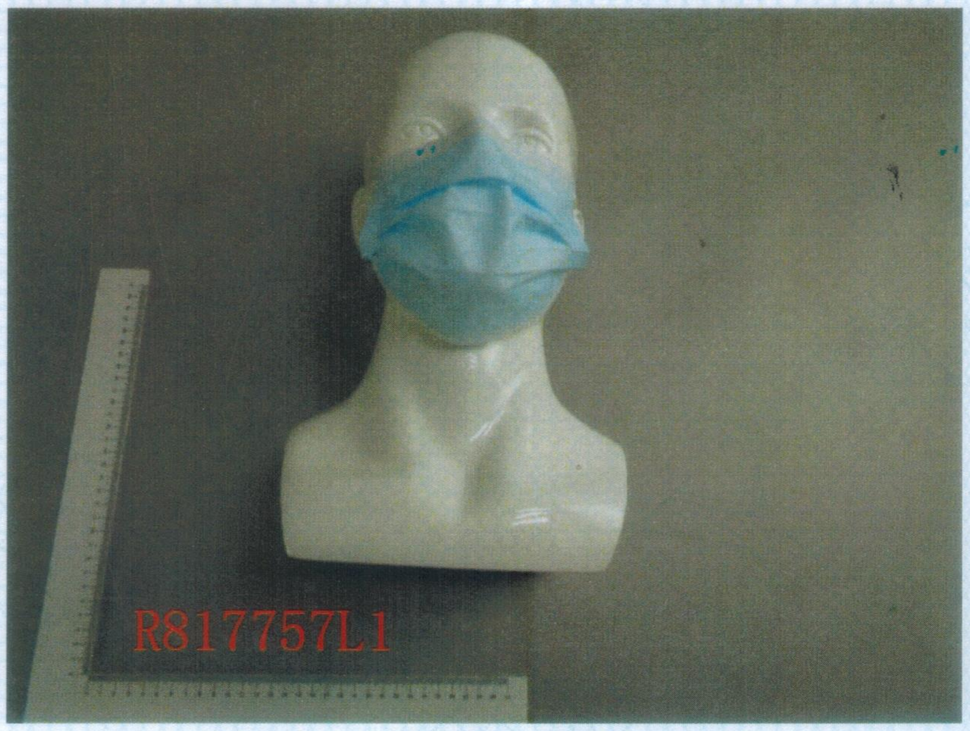
谱尼测试集团上海有限公司
公司地址：上海市松江区文翔东路 99 号 7 幢 2 层　　电话：021-37895599
检测地址：上海市松江区文翔东路 99 号 5 幢、6 幢、7 幢 1 层、7 幢 3 层
上海市徐汇区桂平路 680 号 35 幢 2-4 楼、6 楼

检 测 结 果
(Test Results)

No. BOYBXQSR817757L1

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	IIR 型 Type IIR 限值 (Limit)	检测结果 (Test Results)	单项结论 (Evaluation)	检测方法 (Test Methods)
R817757L1 一次性医用口罩 Disposable Medical Face Mask	细菌过滤效率，% Bacterial filtration efficiency(BFE)	≥98	No.1 99.2 No.2 99.2 No.3 99.0 No.4 98.9 No.5 98.7	符合 Qualified	EN 14683：2019
	压力差，Pa/cm^2 Differential pressure	＜60	23.3	符合 Qualified	EN 14683：2019
	抗溅压力，kPa Splash resistance pressure	≥16.0	＞16.0	符合 Qualified	EN 14683：2019
	微生物清洁度，cfu/g Microbial cleanliness	≤30	＜1	符合 Qualified	EN 14683：2019

样品编号和照片（Sample Number and Photo）：



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———以下空白———
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谱尼测试集团上海有限公司
公司地址：上海市松江区文翔东路 99 号 7 幢 2 层　　电话：021-37895599
检测地址：上海市松江区文翔东路 99 号 5 幢、6 幢、7 幢 1 层、7 幢 3 层
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