

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. Aihara
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戴，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





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 SUNGO TECHNICAL SERVICE INC.
Communications: 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.



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 (Disposable 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



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.

PONY 谱尼测试
Pony Testing International Group
www.ponytest.com



声明
Statement

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This report is invalid without the approver's signatures and special seal of inspection.
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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).
4. 委托单位办理完毕以上手续后，本单位会尽快安排复测。如果复测结果与异议内容相符，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.
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▲ 防伪说明 (Anti-counterfeiting Description):

- (1) 报告编号是唯一的;
The test report has exclusive report code.
 - (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。
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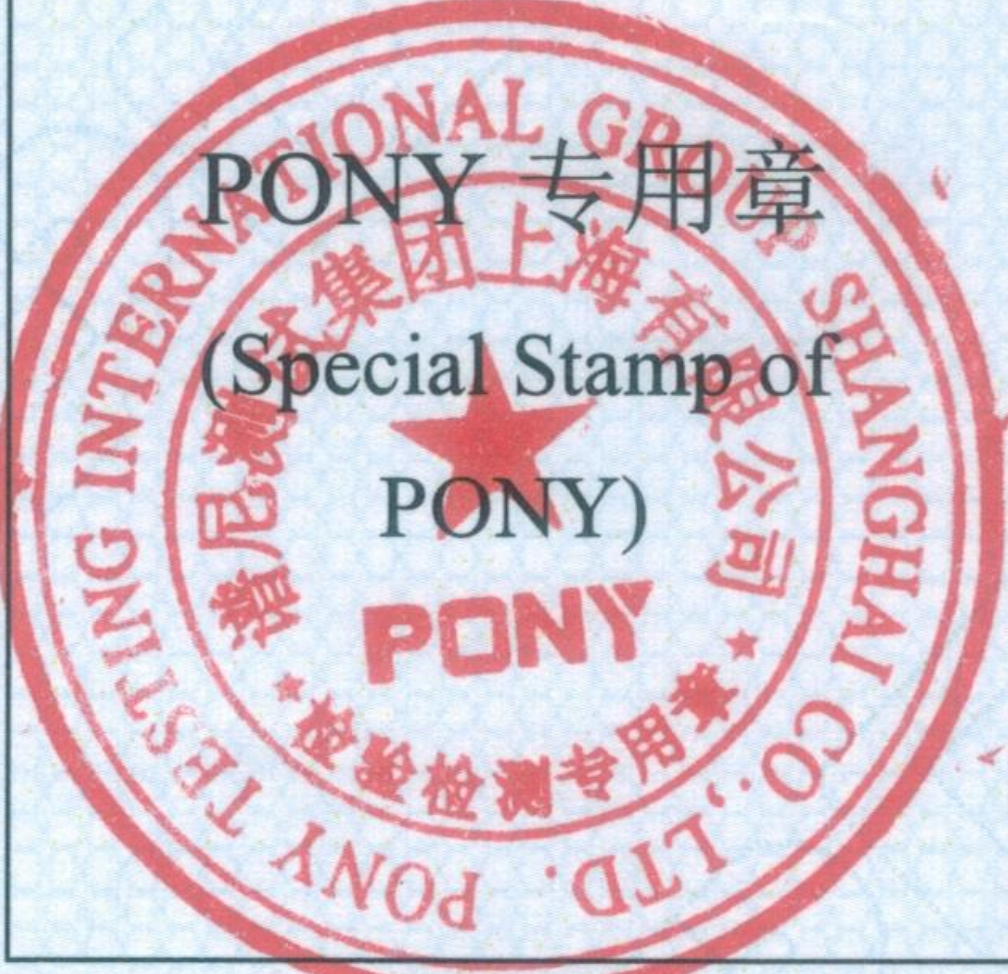



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检测结果
(Test Results)

No. BOYBXQSR817757L1

第 1 页, 共 2 页 (page 1 of 2)

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		
	编制人 (Edited by)	 	
	审核人 (Checked by)		
	批准人 (Approved by)		
	签发日期 (Issued Date)	2020-04-08	

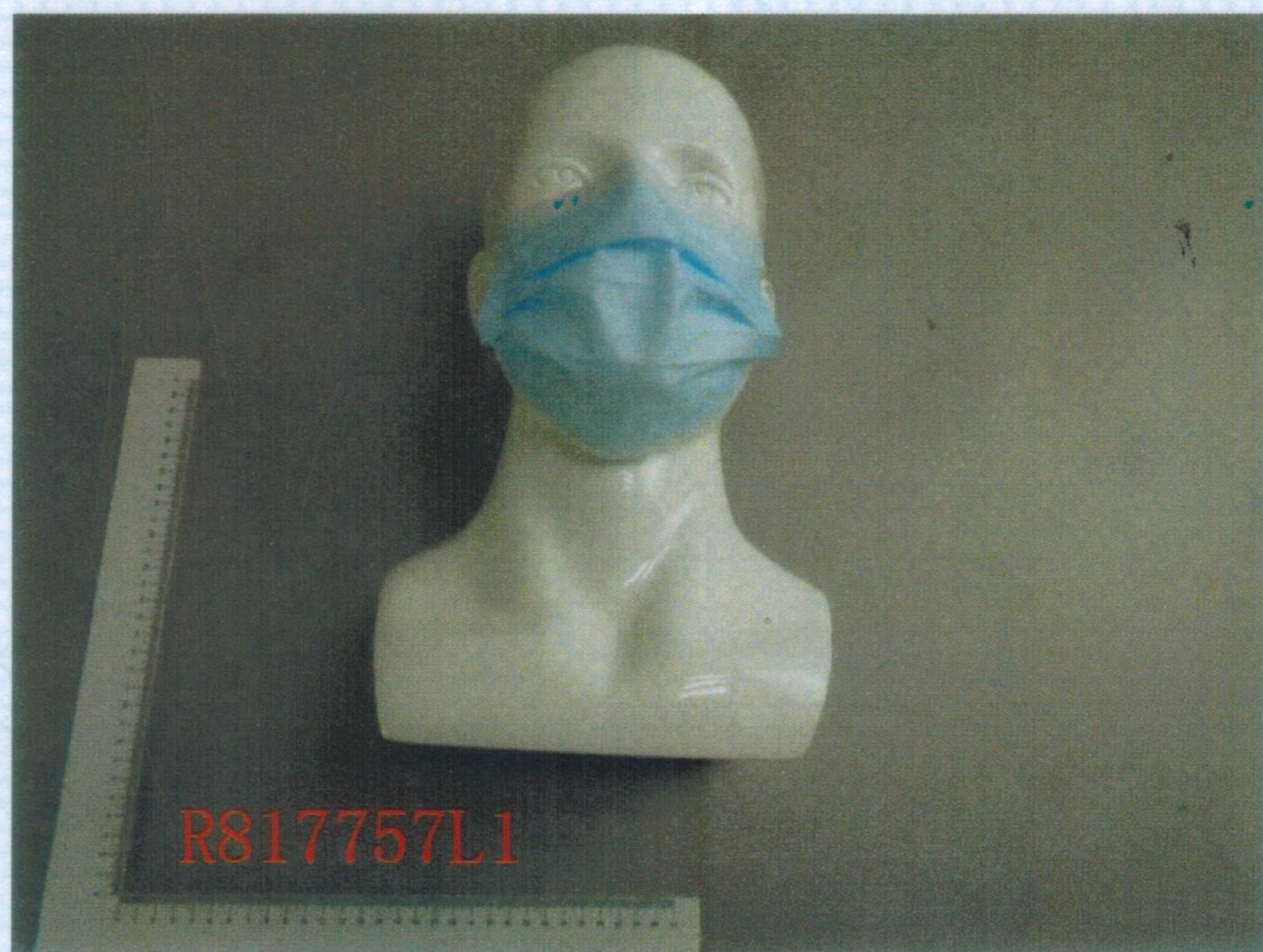
检测结果 (Test Results)

No. BOYBXQSR817757L1

第 2 页, 共 2 页 (page 2 of 2)

样品名称和编号 (Sample Description and Number)	检测项目 (Test Items)	II R 型 Type II R 限值 (Limit)	检测结果 (Test Results)		单项结论 (Evaluation)	检测方法 (Test Methods)
			No.1	No.2		
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	符合 Qualified	EN 14683: 2019
			No.3 99.0	No.4 98.9		
			No.5 98.7			
	压力差, Pa/cm ² Differential pressure	<60	23.3			
抗溅压力, kPa Splash resistance pressure	≥16.0	>16.0				
	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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Pony authenticate the photo on original report only

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(End of Report)

