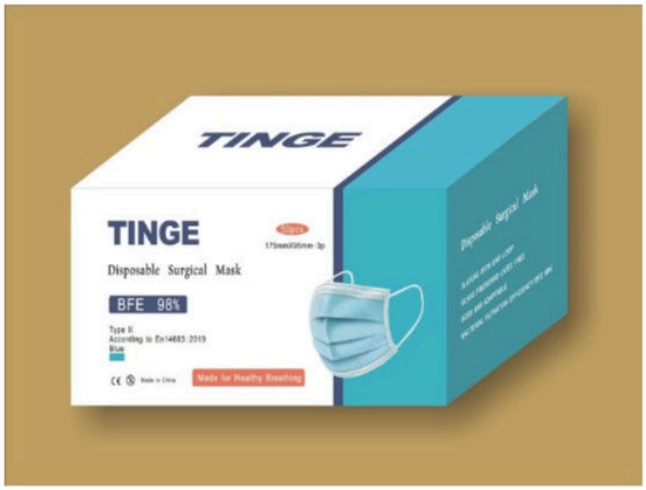
Disposable medical mask

1、 **Finished product drawing：**

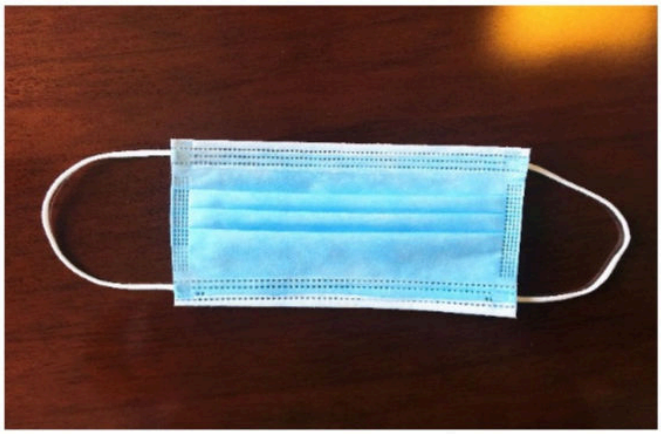
product implementation standards： YY/T0969-2013

EU standard: CE EN14683:2019

Picture of product outer box： A box of 50 tablets.



Size： Plane lug type 175X95mm



Melt-blown fabric BFE99.2、25X175

2、 Product carton picture specification：

Qty： 50pcs×40boxes（2000pcs）

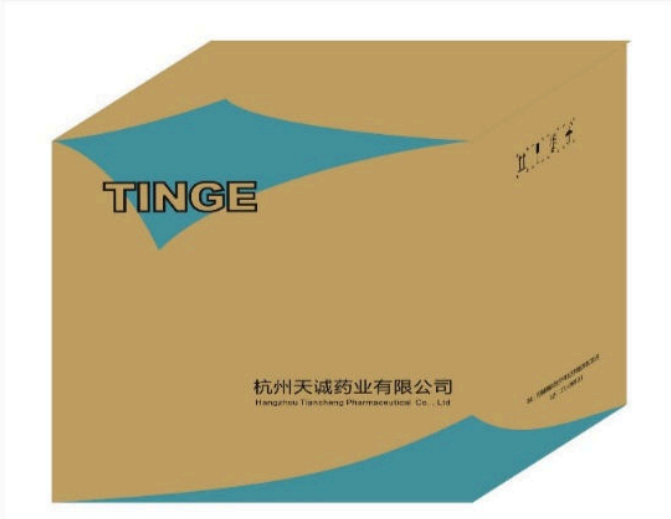
Mwas： 48X42.5 X50.3cm

（G. W.）： 9.5kg （N.W.）： 8.0kg

Validity： 2years

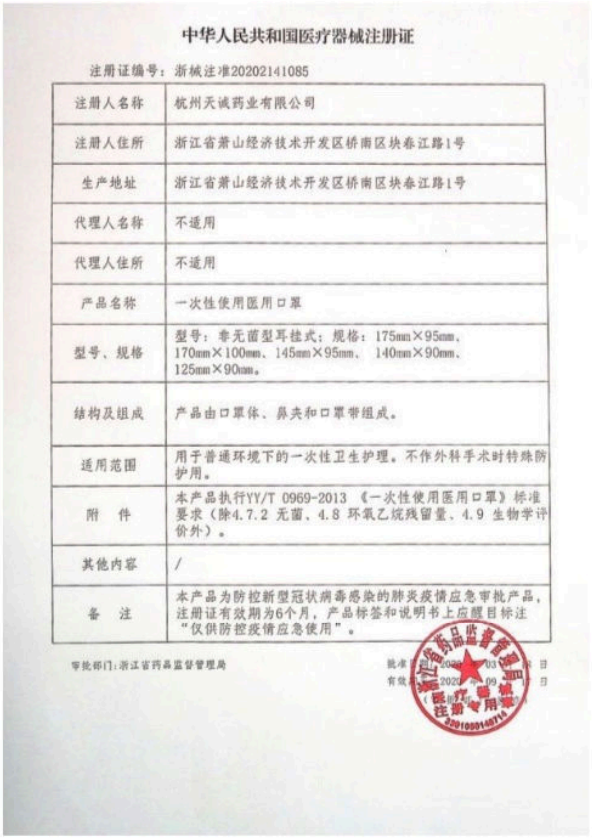
Quality guarantee period： Two years

date of manufacture ： See product code printing



3. **Company qualification**

Registration certificate of medical device B registration certificate of disposable medical mask C production license of medical device



中华人民共和国医疗器械注册证

注册证编号：浙械注准20202141085

注册人名称	杭州天诚药业有限公司
注册人住所	浙江省萧山经济技术开发区桥南区块春江路1号
生产地址	浙江省萧山经济技术开发区桥南区块春江路1号
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	型号：非无菌型耳挂式；规格：175mm×95mm、170mm×100mm、145mm×95mm、140mm×90mm、125mm×90mm。
结构及组成	产品由口罩体、鼻夹和口罩带组成。
适用范围	用于普通环境下的一次性卫生护理。不作外科手术时特殊防护用。
附　件	本产品执行YY/T 0969-2013 《一次性使用医用口罩》标准要求（除4.7.2 无菌、4.8 环氧乙烷残留量、4.9 生物学评价外）。
其他内容	/
备　注	本产品为防控新型冠状病毒感染的肺炎疫情应急审批产品，注册证有效期为6个月，产品标签和说明书上应醒目标注“仅供防控疫情应急使用”。

审批部门：浙江省药品监督管理局

营业执照

（副本）

统一社会信用代码 91330109609128303D (1/1)

名　　称　杭州天诚药业有限公司

类　　型　有限责任公司

住　　所　浙江省萧山经济技术开发区桥南区块春江路1号

法定代表人　潘观根

注册资本　壹仟玖佰肆拾万元整

成立日期　1993年05月22日

营业期限　1993年05月22日 至 2058年05月21日

经营范围　生产：医疗器械（具体范围见《医疗器械生产企业许可证》）。保健食品（具体范围见《保健食品生产许可证》）；卫生用品；抗（抑）菌剂（液体）（净化）（以上经营范围在许可证有效期内方可经营）** 销售：化妆品；收购：本企业所需的原辅材料（限直接向第一产业的原始生产者收购）；生物技术研发；医药信息咨询服务；企业营销策划；房屋租赁、物业服务**（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）

多证合一

登记机关　2017年10月10日

企业应当于每年1月1日至6月30日通过浙江省企业信用信息公示系统向社会公示上一年度年度报

企业信用信息公示系统网址：http://gsxt.zjaic.gov.cn/　　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：浙食药监械生产许20110094号

企业名称：杭州天诚药业有限公司

生产地址：浙江省萧山经济技术开发区桥南区块春江路1号

法定代表人：潘观根

生产范围：旧版:第二类 6801-2-一次性使用无菌手术刀，6856-1-供氧系统，6864-0-其他，6864-2-敷料、护创材料，第三类 6864-2-敷料、护创材料；新版：第二类 14-14-医护人员防护用品***

企业负责人：潘国英

住　　所：浙江省萧山经济技术开发区桥南区块春江路1号

发证部门：浙江省药品监督管理局

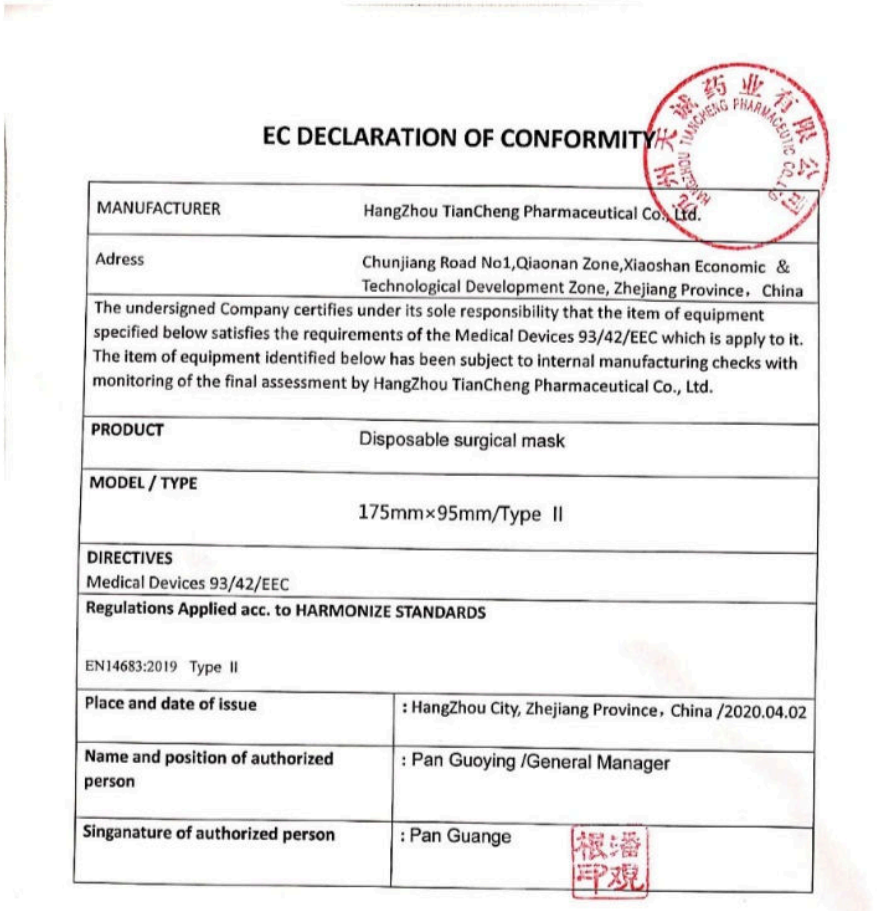
有效期限：至 2021 年 7 月 4 日

发证日期：2020 年 3 月 19 日

国家食品药品监督管理总局制

4. Instructions for export of disposable medical masks (non sterile) to EU

EU medical / non-medical masks need to be attached with CE mark, but the applicable standards are different. In the EU, medical masks belong to class I devices, which are divided into class I non sterile and sterile. CE mark shall be attached according to EU medical device directive 93 / 42 / EEC (MDD) or EU medical device regulation eu2017 / 745 (MDR). The corresponding standard is en14683. The outer packaging or test report and certificate of masks exported to the EU Those with the above contents can be determined as medical masks. Non sterile masks need CE self-compliance declaration, and do not need to pass the certification of the notified body. After preparing the corresponding documents, test reports and other data, the declaration of conformity can be completed by yourself.



EC DECLARATION OF CONFORMITY

MANUFACTURER	HangZhou TianCheng Pharmaceutical Co., Ltd.
Adress	Chunjiang Road No1,Qiaonan Zone,Xiaoshan Economic & Technological Development Zone, Zhejiang Province, China
The undersigned Company certifies under its sole responsibility that the item of equipment specified below satisfies the requirements of the Medical Devices 93/42/EEC which is apply to it. The item of equipment identified below has been subject to internal manufacturing checks with monitoring of the final assessment by HangZhou TianCheng Pharmaceutical Co., Ltd.	
PRODUCT	Disposable surgical mask
MODEL / TYPE	175mm×95mm/Type II
DIRECTIVES Medical Devices 93/42/EEC	
Regulations Applied acc. to HARMONIZE STANDARDS EN14683:2019 Type II	
Place and date of issue	: HangZhou City, Zhejiang Province, China /2020.04.02
Name and position of authorized person	: Pan Guoying /General Manager
Singanature of authorized person	: Pan Guange

Technical Construction File

EN 14683:2019

Medical face masks - Requirements and test methods

Report reference No.	TMZJ20031022146
Compiled by (+ signature)	Stephen Zhang / Test Engineer
Approved by (+ signature)	Kosco Vent / Project Manager
Date of issue	March 10,2020
Reviewing laboratory	Shanghai Global Testing Services Co., Ltd.
Reviewing location	Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Applicant	HangZhou TianCheng Pharmaceutical Co., Ltd.
Address	Chunjiang Road No1,Qiaonao Zone,Xiaoshan Economic & Technological Development Zone, Zhejiang Province
Manufacturer	HangZhou TianCheng Pharmaceutical Co., Ltd.
Address	Chunjiang Road No1,Qiaonao Zone,Xiaoshan Economic & Technological Development Zone, Zhejiang Province
Factory	The same as Manufacturer
Address	The same as Manufacturer
Standard	☒ EN 14683:2019
Review Report Form No.	14683
TRF originator	GTS
Master TRF	Reference No. EN 14683:2019
Review procedure	GTS
Type of Review object	Disposable Surgical Mask
Trademark	-
Model/type reference	175mm×95mm, 170mm×100mm, 145mm×95mm, 140mm×90mm, 125mm×90mm
Rating	175mm×95mm, 170mm×100mm, 145mm×95mm, 140mm×90mm, 125mm×90mm

GLOBAL TESTING SERVICES CO.,LTD. GTS CERTIFICATION

Possible review case verdicts:
- review case does not apply to the test object: N(.A.)
- review object does meet the requirement: P(ass)
- review object does not meet the requirement: F(ail)

General remarks:

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a comma is used as the decimal separator.

The review results presented in this report relate only to the object reviewed.

This report shall not be reproduced except in full without the written approval of the third party.

Testing:	
Date of receipt of review item:	March 08,2020
Date(s) of performance of review:	March 08,2020 to March 10,2020

General product information:

Disposable Surgical Mask

Summary of reviewing:

This review report includes:

Annex I: 1 page(s) of photo documentation.

Copy of marking plate

Disposable Surgical Mask, Model 175mm×95mm, 170mm×100mm, 145mm×95mm, 140mm×90mm, 125mm×90mm HangZhou TianCheng Pharmaceutical Co., Ltd.	Marking CE

4	Classification		--
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type II R	P
5	Requirements		--
5.1	General		--
5.1.1	Materials and construction		--
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	Design		--
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		--
5.2.1	General		--
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)		--
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.	BFE ≥98%	P
5.2.3	Breathability		--
	When tested in accordance with Annex C, the		P

	differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		
5.2.4	Splash resistance		--
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden)		--
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1). To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018 may be applied. In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.		P
5.2.6	Biocompatibility		--
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		P
5.2.7	Summary of performance requirements		--
	Table 1 — [illegible] (reproduced table, see below)		--

[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	Not required	Not required	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

[illegible]

6	Marking, labelling and packaging		--
	Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, § 23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied: a) number of this European Standard; b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

- End of Review Report -

Type of equipment, model: Disposable Surgical Mask 175mm×95mm, 170mm×100mm, 145mm×95mm, 140mm×90mm, 125mm×90mm

Details of:

View:
[X] general
[ ] front
[ ] rear
[ ] right
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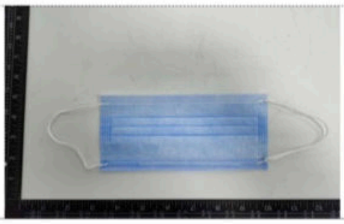

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View:
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- End of Annex I -

5、Disposable medical mask test report

MDST

检 验 报 告

Test Report

报告编号：Z20200669

产 品 名 称：一次性使用医用口罩

规 格 型 号：型号：非灭菌型，规格：175mm×95mm

受 检 单 位：杭州天诚药业有限公司

检 验 类 别：委托检验

浙 江 省 医 疗 器 械 检 验 研 究 院

ZHEJIANG INSTITUTE OF MEDICAL DEVICE SUPERVISION AND TESTING

浙江省医疗器械检验研究院

检 验 报 告

报告编号：Z20200669　　共 6 页 第 1 页

样品名称	一次性使用医用口罩		
规格型号	型号：非灭菌型，规格：175mm×95mm	检验类别	委托检验
委托人/单位	杭州天诚药业有限公司		
受检单位名称	杭州天诚药业有限公司		
制造单位名称	杭州天诚药业有限公司		
取样方式	送样	抽样地点	/
抽样日期	/	抽样基数	/
抽样人	/	样品接受日期	2020-03-09
样品数量	12包（共60只）	样品生产日期	20200309
样品批号/编号	200301		
检验依据	YY/T0969-2013		
检验项目	全性能检验（4.7.2，4.8，4.9除外）		
检验日期	2020年03月09日～2020年03月23日		
检验结论	被检样品所检项目符合YY/T 0969-2013《一次性使用医用口罩》的要求。		

批准：　　审核：　　主检：

职务：授权签字人

日期：2020.03.24　　日期：2020.03.24　　日期：2020.03.24

检 验 报 告

报告编号：Z20200669　　共 6 页 第 2 页

检验地点	省院、宁波实验室			本报告共有3幅照片
分包检验项目	/			
委托人/单位资料	电话	0571-82697225	邮政编码	/
	地址	浙江省萧山祥济技术开发区楼南区块春江路1号		
采用的检验方法	■标准方法； □客户定制的方法； □不实验室随供的方法； □其他方法；			
评估测量不确定度的声明/信息	/			
意见和解释	/			
样品描述	/样品状态描述：　a）结构组成：/；　b）原理、用途：/；　c）主要特征参数：外观、结构与尺寸、鼻夹、口罩带、细菌过滤效率、通气阻力、微生物限度；　d）样品状态：完好。			
其他说明	/			

检 测 结 果 汇 总

报告编号：Z20200669　　共 6 页 第 3 页

序号	检测项目	标准条款	标准要求	实测结果			判定结论
1	外观	4.1	口罩外观应整洁、形状完好，表面不得有破损、污渍	符合			合格
2	结构与尺寸	4.2	口罩佩戴好后，应能贴住佩戴者的口、鼻至下颌	符合			合格
			应符合设计的尺寸，最大偏差应不超过±5%	口罩长度：175mm	1	2	3	合格
					174	175	174	
				口罩宽度：95mm	1	2	3	合格
					94	94	94	
3	鼻夹	4.3.1	口罩上应配有鼻夹，鼻夹自可塑性材料制成	符合			合格
		4.3.2	鼻夹长度应不小于8.0cm	1	2	3	合格
				10.1	9.8	10.1	
4	口罩带	4.4.1	口罩带应舒取方便	符合			合格
		4.4.2	每根口罩带与口罩体连接点处的断条强力应不小于10N	符合			合格
5	细菌过滤效率（BFE）	4.5	口罩的细菌过滤效率应不小于95%	1	2	3	合格
				99.5%	99.6%	99.7%	
6	通气阻力	4.6	口罩两侧面进行气体交换的通气阻力应不大于49Pa/cm²	1	2	3	合格
				27	29	32	
7	微生物限度	4.7.1	细菌菌落总数：≤100CFU/g	28CFU/g			合格
			大肠菌群：不得检出	未检出			合格

检 测 结 果 汇 总

报告编号：Z20200669　　共 6 页 第 4 页

序号	检测项目	标准条款	标准要求	实测结果	判定结论
			绿脓杆菌：不得检出	未检出	合格
			金黄色葡萄球菌：不得检出	未检出	合格
			溶血性链球菌：不得检出	未检出	合格
			霉菌：不得检出	未检出	合格

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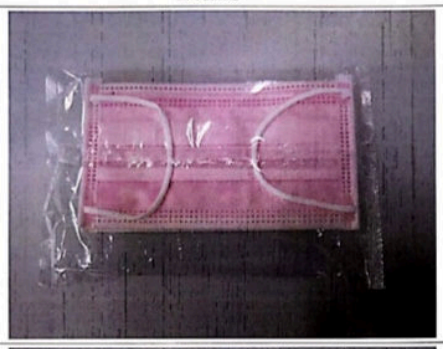
报告编号：Z20200669　　共 6 页 第 5 页

照片粘贴处

第1幅



第2幅

报告编号：Z20200669　　共 6 页 第 6 页

照片粘贴处

第3幅

Bacterial filtration rate (BFE) test results：99.2%

6、Factory production picture

7、Cooperation terms (RMB settlement)

50% of the total payment shall be paid on the day of signing the contract. Both parties shall agree on the capacity delivery form and take the agreed delivery quantity on the same day

50% of the balance before delivery

According to the announcement of the State Drug Administration of the General Administration of Customs of the Ministry of Commerce of the people's Republic of China on the orderly export of medical materials (No. 5 in 2020), it is clear that:

Our company's products: disposable medical masks are among them.

中华人民共和国商务部
MINISTRY OF COMMERCE OF THE PEOPLE'S REPUBLIC OF CHINA

首页 | 机构设置 | 政务公开 | 政务服务 | 互动交流 | 公共服务

首页> 政策发布> 对外贸易管理

商务部 海关总署 国家药品监督管理局公告2020年第5号 关于有序开展医疗物资出口的公告

当前，全球疫情呈加速扩散蔓延态势，在做好自身疫情防控的基础上，有序开展医疗物资出口是强化疫情防控国际合作、共同应对全球公共卫生危机的重要举措。在疫情防控特殊时期，为有效支持全球抗击疫情，保证产品质量安全，规范出口秩序，自4月1日起，出口新型冠状病毒检测试剂、医用口罩、医用防护服、呼吸机、红外体温计的企业向海关报关时，须提供书面或电子声明（模板见附件1），承诺出口产品已取得我国医疗器械产品注册证书（相关注册信息见附件2），符合进口国（地区）的质量标准要求。海关凭药品监督管理部门批准的医疗器械产品注册证书验放。上述医疗物资出口质量监管措施将视疫情发展情况动态调整。

有关医疗物资出口企业要确保产品质量安全，符合相关标准要求，积极支持国际社会共同抗击疫情。

附件：1. 出口医疗物资声明模板.doc

2. 我国相关医疗器械产品注册信息（国家药品监督管理局网站www.nmpa.gov.cn动态更新）.xlsx

商务部 海关总署 国家药品监督管理局

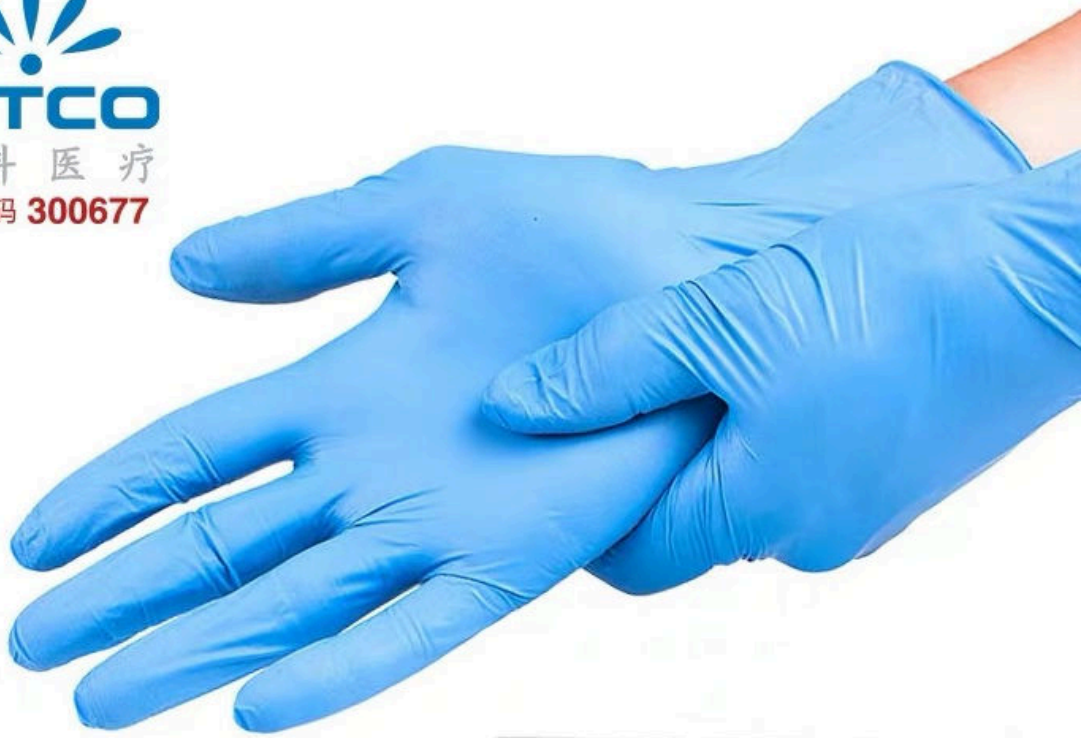
2020年3月31日

675	浙械注准20202141048	一次性使用医用口罩	杭州山友医疗器械有限公司
676	浙械注准20202141050	普通医用口罩	绍兴瑞凯防护用品有限公司
677	浙械注准20202141051	一次性使用医用口罩	浙江科瑞医药科技有限公司
678	浙械注准20202141052	一次性使用医用口罩	浙江实达皮革服饰有限公司
679	浙械注准20202141053	一次性使用医用口罩	浙江佰意智造服饰有限公司
680	浙械注准20202141061	一次性使用医用口罩	宏昌生物医疗科技(平湖)有限公司
681	浙械注准20202141065	一次性使用医用口罩	浙江银达生物技术有限公司
682	浙械注准20202141066	一次性使用医用口罩	宁波健翔包装材料科技有限公司
683	浙械注准20202141073	一次性使用医用口罩	浙江天使医疗器械有限公司
684	浙械注准20202141074	一次性使用医用口罩	杭州可靠护理用品股份有限公司
685	浙械注准20202141076	一次性使用医用口罩	宁波金格奥电器股份有限公司
686	浙械注准20202141078	一次性使用医用口罩	浙江家誉卫生用品有限公司
687	浙械注准20202141079	一次性使用医用口罩	浙江龙德医药有限公司
688	浙械注准20202141080	一次性使用医用口罩	杭州立山皮件有限公司
689	浙械注准20202141082	一次性使用医用口罩	杭州万事利丝绸数码印花有限公司
690	**浙械注准20202141085**	**一次性使用医用口罩**	**杭州天诚药业有限公司**
691	浙械注准20202141086	一次性使用医用口罩	拓胜防护用品（宁波）有限公司
692	浙械注准20202141087	一次性使用医用口罩	浙江隆泰医疗科技股份有限公司
693	浙械注准20202141090	一次性使用医用口罩	金华德邦医疗器械有限公司
694	浙械注准20202141091	一次性使用医用口罩	宁波欧涵医疗器械有限公司
695	浙械注准20202141092	一次性使用医用口罩	浙江艾明德生物科技有限公司
696	浙械注准20202141094	一次性使用医用口罩	绍兴港蜂医用品有限公司
697	浙械注准20202141096	一次性使用医用口罩	永康市巨立防护用品有限公司
698	浙械注准20202141099	一次性使用医用口罩	杭州永利百合医疗器械有限公司
699	浙械注准20202141101	一次性使用医用口罩	浙江蓝天制衣有限公司
700	浙械注准20202141103	一次性使用医用口罩	德普斯医疗器械湖州有限公司
701	浙械注准20202141105	一次性使用医用口罩	浙江蓝天鹤舞控股有限公司
702	浙械注准20202141106	一次性使用医用口罩	浙江建安检测研究院有限公司
703	浙械注准20202141108	一次性使用医用口罩	浙江京环医疗用品有限公司
704	浙械注准20202141110	一次性使用医用口罩	浙江欣富无纺布科技有限公司
705	浙械注准20202141112	一次性使用医用口罩	杭州润恒医疗器械有限公司
706	浙械注准20202141113	一次性使用医用口罩	嘉兴市正群医疗器械有限公司
707	浙械注准20202141117	一次性使用医用口罩	杭州达维先医药科技有限公司
708	浙械注准20202141118	一次性使用医用口罩	浙江欧洁科技股份有限公司
709	浙械注准20202141119	一次性使用医用口罩	江山市美绣服饰有限公司
710	浙械注准20202141122	一次性使用医用口罩	金华家大夫医护用品有限公司
711	浙械注准20202141124	一次性使用医用口罩	德普斯医疗器械湖州有限公司
712	浙械注准20202141125	一次性使用医用口罩	浙江华光胶囊股份有限公司
713	浙械注准20202141126	一次性使用医用口罩	浙江康柏斯医疗科技有限公司
714	浙械注准20202141127	一次性使用医用口罩	冀发集团有限公司
715	津械注准20202140842	一次性使用医用口罩	天津骏发森达卫生用品有限公司

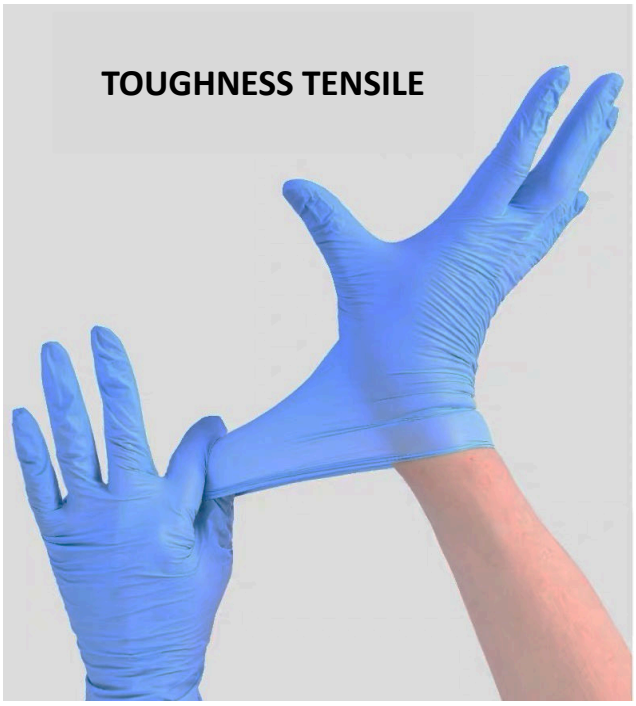
新冠病毒检测试剂 | 呼吸机 | 医用防护服 | 医用防护口罩 | 医用外科口罩 | 一次性使用医用口罩 | 红外体温计

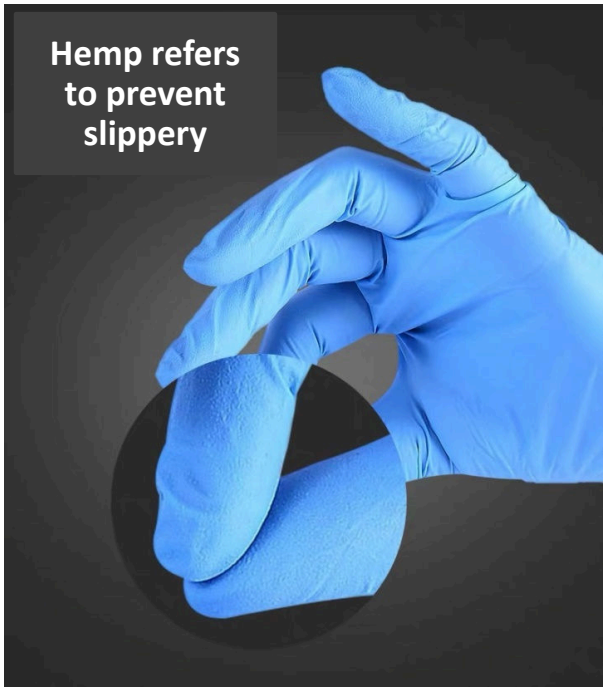
Intco Medical disposable Nitrile gloves

INTCO
英科医疗
股票代码 300677



Without powder
Without smell
Both hand use
Oil proof
Waterproof





Intco Medical disposable PVC gloves

INTCO
英科医疗

Without powder
Without smell
Both hand use
Oil proof
Waterproof

Package information:

Products	Size	N.w.(kgs)	G.w.(kgs)	Package	Package size	Pictures
Nitrile Gloves	S	3.0	4.0	100pcs/box 10 boxes/ package	Outside :33.5*26.5*26.5CM	
	M	3.5	4.5		Inside :24*12.5*6.3CM	
	L	4.0	5.0		1300 Package/20ft FCL	
	XL	4.5	5.5		3300 Package/40ft FCL	
PVC Gloves	S	4.0	5.0	100pcs/box 10 boxes/ package	Outside :33.5*26.5*26.5CM	
	M	4.5	5.5		Inside :24*12.5*6.3CM	
	L	5.0	6.0		1300 Package/20ft FCL	
	XL	5.5	6.5		3300 Package/40ft FCL	

SGS

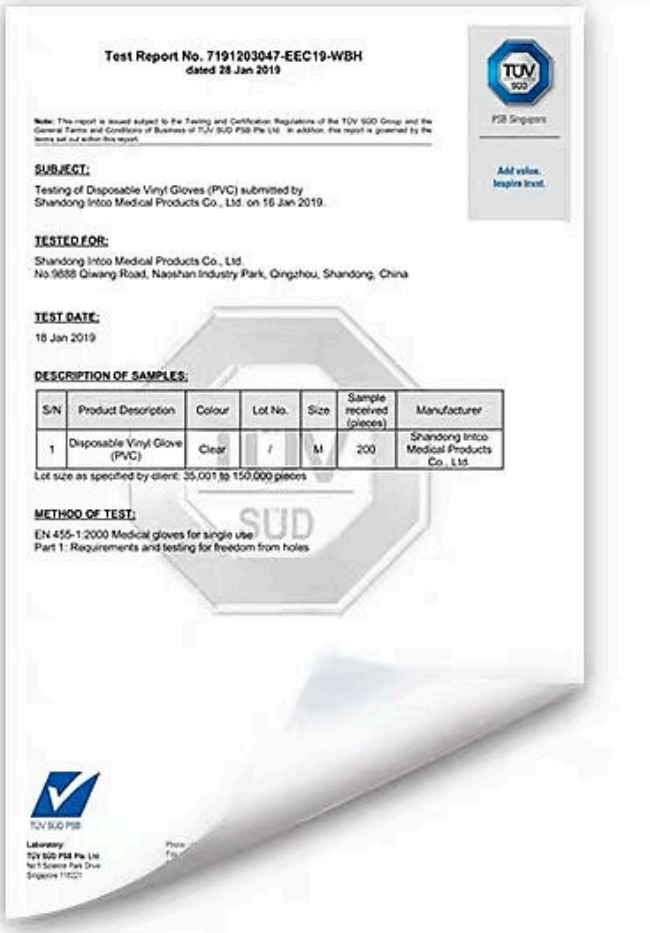
TEST REPORT

No. : GZIN1510045067MR
Date : Oct 30, 2015
Page: 2 of 6

Summary of Results:

No.	Test Item	Test Method	Result		Conclusion
1	Length	ISO 4592:1992	Sample 1	244 mm	/
			Sample 2	241 mm	
			Sample 3	239 mm	
2	Tensile Strength	With reference to ASTM D412-06a(2013) Method A and client's requirement	Sample 1	11.6 MPa	/
			Sample 2	17.5 MPa	
			Sample 3	16.4 MPa	
3	Thickness	ISO 4593:1993	Sample 1	0.067 mm	/
			Sample 2	0.066 mm	
			Sample 3	0.066 mm	

Note: Pass : Meet the requirements;
Fail : Does not meet the requirements;
/ : Not Apply to the judgment.



Test Report No. 7191203047-EEC19-WBH
dated 28 Jan 2019

TÜV SÜD PSB Singapore

Add value. Inspire trust.

SUBJECT:

Testing of Disposable Vinyl Gloves (PVC) submitted by Shandong Intco Medical Products Co., Ltd. on 16 Jan 2019.

TESTED FOR:

Shandong Intco Medical Products Co., Ltd.
No.9888 Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China

TEST DATE:

18 Jan 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Vinyl Glove (PVC)	Clear	/	M	200	Shandong Intco Medical Products Co., Ltd.

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No 1 Science Park Drive
Singapore 118221

Issued to:

Shandong IntcoMedical Products Co. Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/11804-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

697024575

Blue 697024575 601-605

Violet 697024575 631-635

White 697024575 641-645

Black 697024575 651-655

Description:

Five fingered disposable nitrile non-sterile gloves.

Sizes:

6/XS, 6.5/S, 7/M, 8/L, 9/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN 374-4: 2013**
40% Sodium Hydroxide (K)	6	-11.5 %
30% Hydrogen peroxide (P)	2	-9.5%
37% Formaldehyde (T)	3	7.4 %
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0278438/1848
SGS: QDHL1806013113OT, CH:TX:6420074520, CH:TX: 9420020333, CH:TX: 9420029243 CH:TX: 9420026599-1, CH:TX: 9420014953-1, CH:TX: 9420026316-1, CH:TX: 9420614959
TUV: 721642857-2

Signed on behalf of SATRA: Tara Saunders Geoff Graham

Date first issued: 30/01/2019
Date of issue: 30/01/2019

Expiry date: 30/01/2024