MEDICAL DEVICES-QUALITY MANAGEMENT SYSTEMS CERTIFICATE

Certificate No.: CQC19QY20047R0S/46500

We hereby certify that

Xiamen Probtain Nonwoven INC./ Xiamen Probtain Medical Technology Co, LTD.

Unified Social Credit Code: 91350200776019243B

4th Floor,A Area 2th Floor,1th Building,Ji'An Road,Tong'An District, Xiamen,Fujian Province,P.R.China /4th Floor,1th Building,Ji'An Road,Tong'An District,Xiamen,Fujian Province,P.R.China

by reason of its

Quality Management System

has been awarded this certificate for compliance with the standard

YY/T 0287-2017 / ISO 13485:2016

The Quality Management System Applies in the following area:

Manufacture of Disposable Medical Sanitary Materials and Nursing Supplies Within Qualifications

Certified since: November 20, 2019 Valid from: November 20, 2019 Valid until: November 19, 2022

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.
Please access www.cqc.com.cn for checking validity of the certificate.

Signed by: Lu Mei

CHINA QUALITY CERTIFICATION CENTRE

CHINA QUALITY CERTIFICATION CENTRE

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China
http://www.cqc.com.cn

D 0005167

2018年版

EC Declaration of Conformity

Manufacturer:	Xiamen Probtain Medical Technology Co.,Ltd. No.1 Building, No.6 Ji'an Road, Tong'an District, Xiamen City, Fujian Province, 361100, P.R. China
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Product Name:	Sterile single use surgical mask
Model:	MP9017
GMDN Code:	35177
UMDN Code:	12-458

Classification (MDD, Annex IX): Class Is, Rule 1.

Conformity Assessment Route: Annex V of MDD 93/42/EEC

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.
Xiamen Probtain Medical Technology Co.,Ltd. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.
Applied standards:
EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, EN ISO 11607-1:2019, EN ISO 11607-2:2019, EN ISO 11737-1:2018, EN ISO 11737-2:2019, ISO 11135:2014.

Notified Body:	SGS Belgium NV Noorderlaan 87, BE-2030 Antwerpen, Belgium
NB Identification number:	1639
(EC) Certificate(s):	CN20/608241
Expire date of the Certificate:	24 May 2024
Start of CE Marking:	Sep. 2020
Place, Date of Issue:	**Xiamen city, 2020-09-01**
Signature:	
Name:	刘翔
Position:	**General Manager**

Certificate CN20/608242

The management system of

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.

No.1 Building, No.6 Ji'an Road, Tong'an District,
Xiamen, Fujian, 361100, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Desgin and Manufacture of Sterile and Non-sterile Single use Surgical masks, Sterile and Non-sterile Single use Medical face masks, Non-sterile medical protective masks

This certificate is valid from 25 August 2020 until 24 August 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 July 2023
Issue 1. Certified since 25 August 2020

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

HC SGS 13485 2016 0118

EC Certificate Production Quality Assurance System: Certificate CN20/608241

The management system of

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD.

No.1 Building, No.6 Ji'an Road, Tong'an District
Xiamen, Fujian, 361100, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V
Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

Sterile Single Use Surgical masks (type I, Type II, Type IIR)

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 August 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 25 August 2020
and first certified by SGS Belgium NV since 25 August 2020

Certification is based on reports numbered CN/TSN/ 9518

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

格林特卫 GREENCARE | 美润股份 PROBTAIN

White list of Chamber Commerce

www.cccmhpie.org.cn

中国医药保健品进出口商会
服务产业链 助力国际化

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取得国外标准认证或注册的医疗物资和非医用口罩生产企业检索

美润 检索

企业名称（中文）	企业名称（英文）	产品类别	统一社会信用代码	国外注册认证情况
厦门美润医疗科技有限公司	Xiamen Probtain Medical Technology Co,. Ltd	医用口罩	91350212MA333XCG9R	欧盟CE
厦门美润医疗科技有限公司（持证公司：Xiamen Probtain Nonwoven Inc.）	Xiamen Probtain Medical Technology Co., Ltd	非医用口罩	91350212MA333XCG9R	欧盟CE
厦门美润医疗科技有限公司（持证公司：Xiamen Probtain Nonwoven Inc.）	Xiamen Probtain Medical Technology Co.,Ltd	非医用口罩	91350212MA333XCG9R	美国EUA

CE

EC Declaration of Conformity

Manufacturer

Manufacturer:XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Address: 4th Floor,No.1 Building,No.6 Ji'an Road,Tong'an District,Xiamen,Fujian,China

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable Surgical Mask, Model number MP9017
UMDNS-Code: 12447

Type: 17.5cm×9.5cm,14.5cm×9.5cm,12cm×8.5cm

Classification:The medical device has been assigned to class I rule1 according to Annex VIII of the Medical Device Regulation(EU 2017/745).

Conformity Assessment Route:Annex II+III

We confirm our product meet the requirement of Medical Device Regulation and the following harmonized standards.

EN ISO13485:2016
EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008+A1:2013
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
IEC 62366-1:2015
EN 14683:2019+AC:2019

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD 厦门美润医疗科技有限公司 单证专用章

April 21st, 2020

Date

Legally binding signature, Function

CIBG REGISTRATION

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

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

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

f 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
T.I. van Langeveld - Baas

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20202272

Bijlagen
-

Uw aanvraag
18 mei 2020

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

Datum: 29 mei 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 18 mei 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf XIAMEN PROBTAIN MEDICAL TECHNOLOGY 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.

Disposable Isolation Gown
(geen merknaam) (NL-CA002-2020-51458)

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.

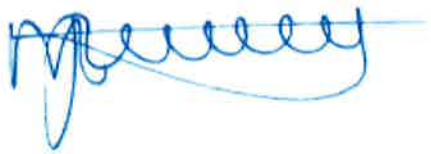
Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. 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



Dr. M.J. van de Velde

Ref. No.: MDRJoJoMA1924-1

MDR EU REP Agreement

Party A甲方: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD

Add地址: ***4th Floor,No.1 Building,No.6 Ji'an Road,Tong'an District,Xiamen,Fujian China***
Contact联系人: 康建立 Jianli Kang

Tel电话: +86 18205948176

Fax传真: +86

Email邮箱: kangjianli@probtain.com

Party B乙方: *SUNGO Europe B.V.*

VAT: NL857821659B01

Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Contact联系人: SUNGO Secretary

Tel电话/Fax传真: +31（0）2021 11106

E-mail邮箱: ec.rep@sungogroup.com

Party A hereby appoints Party B as the EU authorized Representative for their Medical Device with CE mark and Party B accepts the appointment to be the EU authorized Representative for Party A in the market of European Union (E.U.). Both parties enter this agreement as follow:
甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命,为甲方在欧盟市场的CE医疗产品授权代表。双方签署下列协议：

1. Party A 甲方

1.1 Party A assures to provide the updated technical files of each product category with CE mark to Party B (Product categories relevant information please see the appendix A). If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/TXT version), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files in appendix B.
甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档（甲方申请CE认证的产品信息见附录一）。如果甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此而引起的所有后果。甲方必需提交电子文档文件，文件可以PDF/WORD/JPG/TXT格式的任何一种提交。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文档内容的要求，详见本协议"附件二"。

1.2 Party A shall keep the Party B informed of any changes or updates of the mentioned information in attachment 1 at all times.
如果附件1中的文件有任何变化或更新，甲方应及时通知乙方。

1.3 If any accident/near accident of products, including any serious adverse event during clinical

investigation in premarket stage, happens within boundary of E.U., Party A shall help Party B to investigate the reason in time, and complete & submit the initial INCIDENT report together with Party B by using the standard "Manufacturer's Incident Report", to the competent Authority within the timeframe required by the Section 5.1.7 of Guideline's on a Medical Devices Vigilance System(MEDDEV 2.12-1 rev8, Jan, 2013), listed as follows:
如果产品在欧盟境内发生事故或者准事故(包括在上市前的临床调查阶段发生的严重不良事故)，甲方应及时配合乙方调查原因，并同乙方一起在下列医疗器械警戒系统指南（MEDDEV 2.12-1 rev8, Jan, 2013）Section 5.1.7 中规定的期限内完成和提交初始报告。
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by Party A of this threat.
严重威胁公共卫生安全：立即报告（不允许任何无正当理由的延误），报告时限是不应迟于甲方发现该威胁后2个自然日。
Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after party A established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness.
死亡或意外的健康状况严重恶化：立即报告（不允许任何无正当理由延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起10个自然日。
Others: IMMEDIATELY (without any delay that could not be justified) after Party A established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.
其他：立即报告（不允许任何无正当理由的延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起30个自然日。

Party A shall present the investigation result and final report to Party B according to MDR(REGULATION (EU) 2017/745) (MDR products) and the Guidance of vigilance system. If the accident of the product happens out of E.U., Party A shall notify Party B as soon as possible, and Part B should make decision whether to report to competent authority or not.
甲方应在《欧洲共同体理事会法令》按MDR 2017/745 （MDR产品）和《警戒系统指南》规定的时间内向乙方报告调查结果和最终报告。如带CE标志的产品，其事故、准事故发生在欧盟境外，甲方应尽快告知乙方，并由乙方决定是否向主管当局报告。

If the above mentioned accident/near accident of products was known by Party A at first, Party A must notify Party B in one working day and provide the complete report of the investigation, analysis and disposal result of the accident/near accident to Party B by E-mail or other effective means as soon as possible.
如果上述事故、准事故是通过甲方渠道先期获得的，甲方须立即在一个工作日内转告乙方；然后，对事故、准事故的调查、分析和处理结果的报告，用电子邮件或其他有效的方式尽快通知乙方。

1.4 Party A should keep the complete sales list of all of the products exporting to any area of E.U. by electrical documents in English at least 10 years after the last batch product's manufacturing, in order to be provided by Party B for the using to be transferred or inspected to the relevant competent authorities of E.U., Party A shall assure the accuracy and the validity of the data.
甲方出口欧盟地区的所有产品的销售清单（包括OEM的销售清单），在产品停产后至少十年期间，必须用英文文字、电子文档形式保留完整无缺，以备乙方随时用于欧盟官方的调用、检查。甲方应确保其提供的数据的准确性和真实性。

1.5 Party A must notice Party B the complaint record and the result of disposal on the accident of products immediately, and Party A should save, transfer, check-up any of the record according to the clause 1.4.
甲方针对客户/用户的事故或者准事故的投诉、抱怨记录和处理结果，除了应该及时通知乙方以外，所有记录的保存、调用、检查，按照1.4条款办理。

1.6 Party A should appoint one or two persons as the primacy linkman who connect with Party B and deal with the normal daily grind according to this agreement. Information of both Parties'

linkman should be written in appendix C.
甲方需指定一至二人，作为甲、乙双方的第一联络人，主要职责是与乙方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的附件（三）。

1.7 Party A shall fully realize the risk of selling its products to EU market without product registration to relevant competent authority of E.C. If it caused by Party A, such as delay, omittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU market will be prohibited.
甲方应充分认识到本企业产品由于迟缓、延误、疏漏或者隐瞒而造成产品没有登记备案就销售欧盟市场带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入欧盟市场的，甲方将承担罚款、警告，甚至直至吊销CE产品证书和禁止产品进入欧盟市场的后果。

1.8. Part A shall notify of the intention to Part B to carry out a clinical investigation for MDR, or the intention to carry out a performance evaluation for IVDR performed in EU.
甲方应通知乙方在欧盟其对医疗器械进行临床试验的计划，或对体外诊断设备或试剂进行性能评估的计划。

2. Party B 乙方

2.1 About the register for Party A's products with CE mark to relevant competent authority of E.C. (Details are in appendix D), Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Netherlands) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly. The details of the application shall be in the attachments of this agreement. (The charges of products register in EU shall be paid accordingly by Party A and a contract may be signed separately if necessary.)
甲方已取得CE证书的产品按欧盟相关规定（详见协议附件四），必须需要办理CE产品欧盟登记备案的，需先由甲方提出申请，并提供所有符合规定的文件并填写申请表格，经乙方初步认可后，由乙方负责在7个工作日完成初审，5个工作日内提交乙方所在国荷兰主管当局审核申请登记备案的文件。但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请，不在此时间规定之列。提交文件的内容、时间等细节，应该在双方协议的附件中明示。（登记备案的费用甲乙方根据实际注册情况另外商议并签订合同）

If it needs any expenditure by the competent authority, only after getting Party A's approval, then Party A can take on the payment. If Party A's products register fails by Party B's reason, according to EU relevant laws Party B will be given a warning, penalty and even the qualification of the European Representative will be revoked.
如果需要任何主管机构审核上述登记备案如需要收取相关费用的，需经甲方同意方可由乙方代为支付。如果由于是乙方的原因，甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的，根据欧盟有关法律法规，乙方将受到警告、罚款、吊销担任欧盟代表资格的处罚。

2.2 Party B shall reserve technical files of each category of Party A's products with CE mark, and take up the responsibility of keeping, confidentiality and submission. The technical files shall be reserved at least 10 years after the last batch product's manufacturing. Once competent authority needs the technical files (including new edition technical files which had already registered) of each category of Part A's products with CE mark. Party B should send them to competent authority within ten working days.
乙方应保留甲方每一大类获得CE标志产品的技术电子版文档，并负保管、保密和提交当局的责任。该文档至少保存至最后一批产品停产十年后。一旦欧盟主管当局需要获得CE标识产品的技术文件（含已备案的技术文件的新版本），乙方负责在10个工作日内递交欧盟主管当局。

2.3 Party B would not be responsible for the file content. All the documents, such as sales list and complain records are deemed confidential information; Party B have the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.
乙方不对甲方提交的文件内容负责，乙方对甲方提供的销售清单、投诉记录等文件，负责递交欧

盟相关机构审阅并负有保管、保密的责任。

2.4 Party B permits Party A to use part B's name and address for the purpose of inclusion/printing on all packaging, labeling and instruction for use, of products that carry CE Marking and that have been represented by Party B.
乙方允许在被乙方代表的加贴CE标志的甲方产品的包装、标签、说明书、宣传册等上面加印乙方名称地址作为甲方的欧盟授权代表。

2.5 Party B shall keep following files of party A's products with CE mark at the disposal of the national authorities, at least five years after the last batch product's manufacturing. Minimum documents are:
1) Declaration of conformity,
2) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
3) Notified Body certificate (where relevant),
4) Post market surveillance process and data, vigilance reports and complaints, processes and data,
5) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
6) Relevant clinical data / notification,
7) Details of any distributors / suppliers putting the CE marked devices on the market,
8) Incident reports and corrective actions taken.
乙方应保留甲方以下与CE 标志产品有关的资料供主管当局使用，至少保存至最后一批产品出厂后十年。这些资料至少应包括：
1)符合性声明
2)标签、包装、说明书副本（所有上市国家要求的语言的版本）
3)公告机构证书（适用时）
4)上市后监督过程和数据、警戒报告以及投诉、处理和数据
5)与欧盟成员国上市监督调查有关的技术文件
6)相关的临床数据/通知
7)经销甲方CE标志医疗器械的经销商/供方细节
8)事故报告及采取的纠正措施

2.6 Party B must keep Party A informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning following shall be covered.
乙方应通知甲方所有有关其在欧盟上市医疗器械的信息，至少包括：

2.6.1Safeguard Clause保护条款
"Where a Member State ascertains that a medical devices, when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service."
If the relevant Competent Authority contacts the Party B about its interim measures to withdraw Party A's device(s) from the market or prohibit or restrict their being placed on the market or put into service, Party B should immediately communicate such measures to Party A and advise Party A as to the implications of this decision.
When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the manufacturer or his authorized representative".
If the relevant Competent Authority contacts Party B, Party B should immediately communicate such information to Party A and advise Party A as to the implications of this decision.
"当一个成员国确信一个医疗器械在正确安装、维护和按照预期用途使用情况下，可能会危害患者、使用者、（适用时）其他人员或财产的健康和/或安全时，应采取所有适当的临时措施以将医疗器械撤出市场、禁止或限制器上市"。

如果有关主管当局就有关对甲方医疗器械采取撤出市场、禁止或限制上市的临时措施联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。
当欧盟委员会认为国家的措施不合理，应立即通知采取措施的成员国、制造商或其欧盟授权代表。
如果有关主管当局联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。

2.6.2警戒Vigilance

If the relevant Competent Authority contacts Party B about its assessment outcome of an incident of Party A's medical device, Party B should immediately communicate such information to the manufacturer and advise Party A as to the implications of this decision.
如果欧盟主管当局通知了乙方关于甲方产品发生的事故的决定，乙方应立即就此联系甲方并且使甲方知晓主管当局的决定。

Party B shall notify any information about the products with CE mark within boundary of E.U. to Party A, including any claims of customers that produce the same CE marked products.
乙方应将获得的有关CE产品在欧盟境内的任何消息(包括客户投诉)及时通知甲方。

2.6.3If any accident/ near accident of products (CE marked products, premarket clinical investigation products and performance evaluation products) happens within boundary of E.U., Party B shall notify Party A within 3 working days after receiving the claims of customers and feedback about the product, and execute vigilance system of medical device products under the assisting of Party A, and also make initial report, investigation result and final report to competent authority of country in which the accident happens.
如果带有CE标志的产品，上市前临床试验的产品以及进行性能评估的产品在欧盟境内发生事故或者准事故，乙方应在收到或得知有关甲方产品的投诉或反馈信息3个工作日内及时通知甲方，并在甲方的协助之下调查原因，同甲方一起负责完成初始报告。乙方负责把完成的初始报告、调查结果和最终报告向欧盟主管当局提供。

2.7 Upon receiving the notice about the intention to carry out a clinical investigation for MDR, and the intention to carry out a performance evaluation for IVDR in EU, Party B shall notify communicate the information on the manufacturer and on the device to the Competent Authorities of the Member State in which he has his registered place of business. If any serious adverse events during clinical investigation, i.e. in the premarket phase, Party B Shall fully record and immediately notify to all Competent Authorities of the Member States in which the clinical investigation is being performed.
乙方需要在收到甲方关于在欧盟境内进行医疗器械的临床试验计划，和体外诊断设备或试剂的性能评估计划的通知后，需将相关信息通知所在国的主管机构CA。如果在临床调查中发生严重不良事件，乙方应及时对其进行完整记录并立即告知进行临床调查所在地的主管当局。

2.8 Party B shall appoint one or two persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in appendix C.
乙方需指定一至二人，作为甲、乙双方的第一联络人，主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的附件（三）。

3. Jurisdiction & Duration 管辖权与有效期

3.1 This agreement is subject to the laws and jurisdiction of The Kingdom of Netherlands.
本协议是荷兰的法律制约和管辖。

3.2 This agreement is valid for the duration till 2025/3/5 and it becomes immediately effective from the signature date of Company A.
该协议自甲方签署之日起立即生效，有效期至2025年3月5日。

3.3 During the implementation of the agreement, this agreement will be terminated automatically when:

在协议执行期间内，下列日期为本协议的自动终止日期：

1) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.

甲方的CE证书因故被发证机构暂时吊销/关闭/收回之日；

2) Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or before using CE mark for "self declaration" products. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.

甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效。在本失效之日起的60天内，为了能够方便甲方聘请新的欧盟代表及更改CE证书等相关工作，乙方可以代为继续行使欧盟代表日常事务。乙方应该将与甲方失效的协议信息及时报公告机构备案。

3) Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.

甲方没有按协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

Company A: May 15, 2020
Date

Signature

Company B: 2020.5.15
Date

Signature

Appendix A

For the following product categories:
申请CE认证的产品名称：

1	**Disposable Medical Face Mask**	**Class I**	一次性医用口罩（非灭菌）
2	**Disposable Isolation Gown**	**Class I**	一次性隔离衣（非灭菌）
3			
4			
5			
6			

Appendix B

提交欧盟代表的《技术文件目录》

	Contents	文件清单
Part A		
1	Name, Postal Address of Manufacturer/ EU Representative	制造商和欧洲代表的名字、地址
2	A listing of all manufacturing sites covered by the quality system	质量体系所涉及的全部制造场所清单
3	Product description	产品描述
3.1	Product name, classification of the device and accessories	产品名字、器械及附件的分类
3.2	List of accessories (if applicable)	产品附件清单（适用时）
3.3	Specification, model and article numbers	规格、型号及货号
3.4	Chosen conformity assessment path	符合性评价路径
3.5	Intended use	预期用途描述
3.6	Integral parts of the sales unit	主要的销售单元（适用时）
3.7	A brief product history (including existing regulatory approvals)	简要的产品历史（包括现有的管理审批）
4	List of harmonized standards	适用的标准清单
5	GSPR checklist	通用安全和性能要求检查表
6	Overall manufacturing and inspection plan of the product	产品的总体生产或质量控制方案
7	Risk analysis	风险分析
8	Clinical report	临床报告
9	Labelling, inl. Product labels and package labels	标签，包括产品标签、包装标签
10	Instruction for use, patient information, advertising material	使用说明、患者信息、广告材料
11	Declaration of conformity	符合性声明
Part B		
12	Information concerning the quality system specific to the product	与产品有关的质量体系的信息
13	Detailed descriptions of the product	详细的产品描述
13.1	Design drawings and product specifications	设计图及产品技术规范
13.2	Packaging and specification	包装条件及规格
13.3	Description of the manufacturing processes	生产过程描述
13.4	Raw materials and suppliers	原材料和供方
14	Test, verification and evaluation report	试验、验证及评估报告
14.1	Sterile method and validation	灭菌方法和验证的概述，灭菌证书（适
14.2	Packaging verification (if applicable)	包装验证（适用时）
14.3	Chemical, physical and biology test, verification and evaluation report	化学、物理和生物学试验、验证或评估报告
15	Clinical datas	临床数据
15.1	Preclinical Evaluation, Expert Opinions	临床前评估，专家意见
15.2	Clinical plan	临床方案
15.3	Clinical datas	临床数据
15.4	Clinical Summary, Expert Opinions	临床总结，专家意见
15.5	Clinical report	临床报告
15.6	Relevant Literature	相关文献
16	Post market surveillance system	上市后监管系统

A/B部分文件必须在需要时向欧盟代表处随时以书面或电子文档的形式提供最新版本；
Technical documents (the latest version) including Part A&B shall be submitted to the EU representative in written or electronic form if required.
B部分文件不限于以上所列项目 Documents in SUNGO are not limited to the above-mentioned content.

Appendix C

《甲、乙双方第一通知人（联络人）以及联系方式》
Party A甲方: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Add地址: 4th Floor,No.1 Building,No.6 Ji'an Road,Tong'an District,Xiamen,Fujian China
Contact联系人: 康建立 Jianli Kang
Tel电话:
Mob手机: 18205948176
E-mail邮箱: kangjianli@probtain.com

Party B乙方: SUNGO Europe B.V.
VAT：NL857821659B01
Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact联系人: SUNGO Secretary
Tel电话: +31(0)2021 11106
E-mail邮箱: ec.rep@sungogroup.com

备注事项：
甲、乙双方中的任何一方，一旦对上述信息做任何修改、调整或取消的，需书面/邮件方式及时通知对方。如果由于没有及时通知而造成一方的信息无法转达给另一方之错误的，由过错一方承担由此引起的相关责任。
If any of the above information is changed, adjusted or canceled, the manufacturer and EU REP shall inform the other party in email or written form without delay, If any mistake arise from one party failed to notify the other party timely, the related responsibility shall be undertaken by the guilty party.

Appendix D

《CE产品欧盟登记备案的条件、程序及提交的文件》Registration conditions, procedure and submissions

一、申请的前提条件：Prerequisites of Application

1.生产商已经取得CE证书的产品（或者自我声明/公告的产品），是否办理欧盟地区产品登记备案手续，由生产商视本企业CE产品出口欧盟地区的实际情况，自行决定是否需要办理此项手续。
The manufacturer who has obtained CE certificate（self declaration or issued by Notified Body) for their products may decide whether to go through the registration procedure according to the actual exporting situation in the European Union.

2.但是，如果生产商CE产品一旦有出口欧盟市场计划，且产品是以企业自己的名义出口欧盟市场的，根据欧盟对CE医疗器械产品的准入规定，生产商必须事先向欧盟代表提出申请，由欧盟代表代为提交所有的申请文件。这里所谓“以企业自己的名义出口欧盟市场”的含义是指：任何销售到欧盟地区的CE产品，在产品的任何之处（含产品内、外包装、说明书等），出现制造商任何信息的，既为“以企业自己的名义出口欧盟市场”，该企业的产品必须事先在欧盟申请办理登记备案手续。否则，由此而引起的后果，由生产商承担。
But, if the manufacture plans to export products to EU market and exports in their own name, the manufacture shall apply to the EU REP firstly according to the CE product access rule of medical device, and then the EU REP shall submit all the application files. 'Export to the EU market in manufacturer's own name' means the manufacturer's information showed on any place (including product inside, outer package, operation manual, etc.) of any CE products exported to EU region. The product must apply for registration in EU region in advance. Otherwise, the resulting consequences shall be undertaken by the manufacturer.

3.如果在荷兰申请登记备案成功，原则上无需再向欧盟其他国家和地区申请办理相关产品的登记备案手续。If successfully registered in the Netherlands, in principle, there is no need to apply for the relevant product registration in other EU countries and regions.

二、申请的程序：Application procedure:

1.如果生产商决定为CE产品办理登记备案手续的，生产商应首先向欧盟代表提出申请并按规定提交所有相关登记备案材料和填写申请表格，经欧盟代表审核认可后由欧盟代表代为向荷兰卫生主管当局提交相关申请登记备案材料。If the manufacturer decides to register the CE products, the manufacturer shall firstly apply to their EU REP and submit all relevant materials including completed application forms. The EU REP shall review the documents and then submit them to the Netherlands Health administration Bureau for registration.

2.如果由于生产商提交的材料不齐备或有误被荷兰卫生医疗主管部门退回而延误登记备案的，由生产商按照要求修订、补充申请材料以后，由欧盟代表办理再次申请手续。If the submitted documents are not complete or have errors, the Netherlands Health administration Bureau will return the application and may cause delay of the registration. The manufacturer shall revise and supplement the application documents according to the requirements, and then re-apply the CE registration through EU REP.

3.目前，荷兰卫生主管部门对相关的登记备案信息，采取有条件的开放，即尚未开通对所有公众查询上述登记备案信息的平台。At present, the Netherland Health administration Bureau conditionally open the relevant CE registration information which means the CE registration information platform is not yet open to public.

三、办理登记所需要的文件（英文电子版本）：Registration required documents (electronic version in English)

1.企业的书面申请表格；（格式由欧盟代表统一提供）Application form(the format provided by EU REP)

2.CE证书：CE Certificate;

3.每一大类产品的CE技术文件；（除了PART A部分以外，临床数据、风险管理等内容是必需的；文件格式只接受电子PDF/JPG/TXT）：each product categories CE technical file (except Part A, Clinical data and risk management must be submitted; documents only accept electronic copy (PDF/JPG/TXT version).

4.产品最近的符合性声明（latest DECLARATION OF CONFORMITY）；

5.出口欧盟地区的销售清单；（格式由欧盟代表统一提供）Product sales list exported to EU market.(the format provided by EU REP)
6.企业合法拥有的商标或品牌的图案实样照片；Legally owned enterprise trademark or brand photos;
7.出口原包装实样和带CE标志产品标签的照片；Picture of exported product in original package and label with CE mark.
8.企业联系人及联络方式；企业网站地址，Contact information and website.

四、登记的撤消与失效：Withdraw and invalidation of registration
1.CE证书失效或因故被发证机构吊销、关闭、收回；CE certificate invalid or withdrew or canceled by releasing authority.
2.生产商、欧盟代表双方就《欧盟代表协议》的中止或失效；Termination or expiration of EC REP Agreement.
3.企业已登记备案产品，长期没有出口欧盟地区的记录；The product has been registered but there is no record of exporting to the EU region in a long-term.
4.其他。Others

JCFM-2

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检 测 报 告

(Test Report)

No. GOLD239C189575L1

样品名称 (Sample Description)	一次性使用医用口罩 Disposable Surgical Mask
委托单位 (Applicant)	厦门美润医疗科技有限公司 XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD

PONY 谱尼测试
Pony Testing International Group

声 明
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3. 委托单位对报告数据如有异议，请于报告完成之日起十五日内（初级农产品报告请于报告收到之日起五日内）向本单位书面提出复测申请，同时附上报告原件并预付复测费。
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.

5. 不可重复性或不能进行复测的实验，不进行复测，委托单位放弃异议权利。
Tests that can not be repeated and tested shall not be carried out again.

6. 委托单位对样品的代表性和资料的真实性负责，否则本单位不承担任何相关责任。
The applicant should undertake the responsibility for the provided samples' representativeness and document authenticity. Otherwise, PONY has not any relevant responsibilities.

7. 本报告仅对所测样品负责，报告数据仅反映对所测样品的评价，对于报告及所载内容的使用，使用所产生的直接或间接损失及一切法律后果，本单位不承担任何经济和法律责任。
This report is only responsible for the provided sample. The test results only represent the evaluation of the tested sample. PONY will not be responsible for any economical or legal liability generated from direct or indirect usage of the test report.

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苏州实验室：(0512)62997900　太原实验室：(0351) 7555762　宁波实验室：(0574)87977185　成都实验室：(028) 87702708

检测结果
(Test Results)

No. GOLD239C189575L1

样品名称 (Sample Description)	一次性使用医用口罩 Disposable Surgical Mask	样品规格 (Sample Specification)	17.5*9.5cm
委托单位 (Applicant)	厦门美润医疗科技有限公司 XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD	商标 (Trade Mark)	——
到样日期 (Received Date)	2020-08-04	生产日期或批号 (Manufacturing Date or Lot No.)	2020.01.28 F-wk20200128
检测日期 (Test Date)	2020-08-04~2020-08-13	样品等级 (Sample Grade)	——
样品状态 (Sample Status)	正常 Normal	检测类别 (Test Type)	委托检测 Commissioning Test
检测项目 (Test Items)	见下页 See next page	检测环境 (Test Environment)	符合要求 To meet the requirements
检测方法 (Test Methods)	见下页 See next page		
所用主要仪器 (Main Instruments)	口罩颗粒物过滤效率及气流阻力测试仪 等 Respirator particle filtration efficiency and airflow resistance tester etc.		
备注 (Note)	1.型号：平面型 MP9017 Model：Planar MP9017 2.生产单位/受检单位：厦门美润医疗科技有限公司 Manufacturer/Tested company：XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD 3.以上样品信息由委托单位提供 The information of sample was provided by the applicant 4.该报告中检测方法由委托单位指定。 The testing methods mentioned in this report were designated by the applicant.		
PONY 专用章 (Special Stamp of PONY)	编制人 (Edited by)	张剑	
	审核人 (Checked by)	224	
	批准人 (Approved by)	[illegible]	
	签发日期 (Issued Date)	2020 年 08 月 13 日	

谱尼测试集团股份有限公司
公司地址：北京市海淀区锦带路 66 号院 1 号楼 5 层 101
检测地址：北京市海淀区锦带路 66 号院 1 号楼
电话：010-83055000 传真：010-82619629

检 测 结 果
(Test Results)

No. GOLD239C189575L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	检测结果 (Test Result)			检测方法 (Test Method)
1	细菌过滤效率（BFE）Bacterial filtration efficiency(BFE)	%	>99.99			BS EN 14683:2019 附录 B Appendix B
			99.96			
			99.82			
			99.96			
			99.91			
2	压力差 Differential pressure	Pa/cm^2	A	B	C	BS EN 14683:2019 附录 C Appendix C
			1-1	23.2	26.1	
			1-2	26.9		
			1-3	26.3		
			1-4	26.2		
			1-5	27.8		
			2-1	23.1	26.9	
			2-2	28.7		
			2-3	27.0		
			2-4	29.6		
			2-5	26.2		
			3-1	27.6	27.0	
			3-2	31.0		
			3-3	27.1		
			3-4	23.0		
			3-5	26.5		
			4-1	25.3	26.0	
			4-2	23.0		
			4-3	26.7		
			4-4	25.7		
			4-5	29.1		
			5-1	26.9	25.8	
			5-2	22.4		
			5-3	29.0		
			5-4	24.3		
			5-5	26.2		

谱尼测试集团股份有限公司
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电话：010-83055000 传真：010-82619629

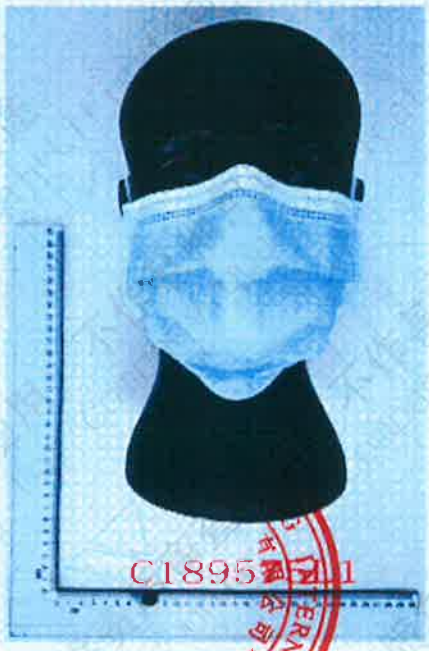
检测结果
(Test Results)

No. GOLD239C189575L1

序号 (S/N)	检测项目 (Test Item)	单位 (Unit)	检测结果 (Test Result)	检测方法 (Test Method)
3	微生物洁净度 Microbial cleanliness	cfu/g	<1	BS EN 14683:2019 附录 D Appendix D
			<1	
			<1	
			<1	
			<1	
4	抗溅压力 Splash resistance pressure	kPa	32 个试样均＞16.0 Splash resistance pressure of 32 samples were all greater than 16.0	ISO 22609:2004

备注 Note：A-试样编号-测试区域编号 Test Specimen number-Test area number；B-每个测试区域的压力差 Differential pressure for each test area；C-每个试样的平均压差 The averaged differential pressure for each test specimen。

照片 Photo：



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(End of Report)

TEST REPORT FOR KIDS MASK

中国认可
国际互认
检测
TESTING
CNAS L0599

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
4TH FLOOR, NO.1 BUILDING, NO.6 JI'AN ROAD, TONG'AN DISTRICT, XIAMEN, FUJIAN, CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035260218001TX
DATE: Jul 01, 2020 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION

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

Sample Description	:	(A)3 ply face mask medical - for kids (Claimed Type IIR)
SGS Internal Ref No.	:	TJHL2006003587MD
Style No.	:	MP9017 14.5*9.5CM
Sample Color	:	(A)blue
Manufacturer	:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Lot No./Batch No.	:	Not provided
Country of Destination	:	EUR
Country of Origin	:	China
Item No.	:	MP9017 14.5*9.5CM
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 11, 2020
Testing Period	:	Jun 11, 2020 - Jul 01, 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).

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

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods **Clause 5.2 Performance Requirement**	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial filtration efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~145 mm x 150 mm
Test Area	:	~60 cm^2
Test Side	:	Inside
Flow Rate	:	28.3 l/min
Positive Control Average	:	2242.5 CFU
Negative Monitor Count	:	< 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.8	99.9	99.9	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%

Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location	:	5 random areas for each specimen (face mask)
Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area	:	4.9 cm^2
Flow Rate	:	8 l/min

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	30	30	30	29	29

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Fail	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			30				
Overall result:			Acceptable				

Remark:

1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

Clause 5.2.5 Microbial Cleanliness

(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.74	3	1.09
2#	2.76	3	1.09
3#	2.79	<3	<1.08
4#	2.79	3	1.08
5#	2.70	6	2.22

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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SURGICAL MASK TEST REPORT
YY0469-2011

广检集团 GTTC

MA 170000113982 ilac MRA CNAS

TEST REPORT

(Electronic version)

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: HDLE-3766-24

No:200109316 ISSUE DATE:2020-05-07

APPLICANT: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD
ADDRESS: 4TH FLOOR, BUILDING 1, NO.6 JI'AN ROAD TONGAN DISTRICT, XIAMEN, CHINA

INFORMATION CONFIRMED BY APPLICANT:

DISPOSABLE SURGICAL MASK

QUANTITY: FIFTY PIECES

DATE RECEIVED/DATE TEST STARTED: 2020-05-07

CONCLUSION:

BACTERIAL FILTRATION EFFICIENCY	M
COLIFORM GROUP	M
TOTAL AMOUNT OF BACTERIAL COLONY	M
TOTAL AMOUNT OF FUNGUS COLONY	M
PSEUDOMONAS AERUGINOSA	M
STAPHYLOCOCCUS AUREUS	M
HEMOLYTIC STREPTOCOCCUS	M
APPEARANCE[3 PIECES]	M
STRUCTURE AND SIZE[3 PIECES]	M
NOSE CLIP[3 PIECES]	M
MASK STRING[3 PIECES]	M
RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD	M
PARTICLE FILTRATION EFFICIENCY	M
FLAME RETARDANT PERFORMANCE	M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"——" -NO COMMENT

REMARK:
THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200088100.
ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).
COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.
THE EXPERIMENT WAS CARRIED OUT AT No. 1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY: 郭子山

ZiShan Guo SENIOR ENGINEER

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

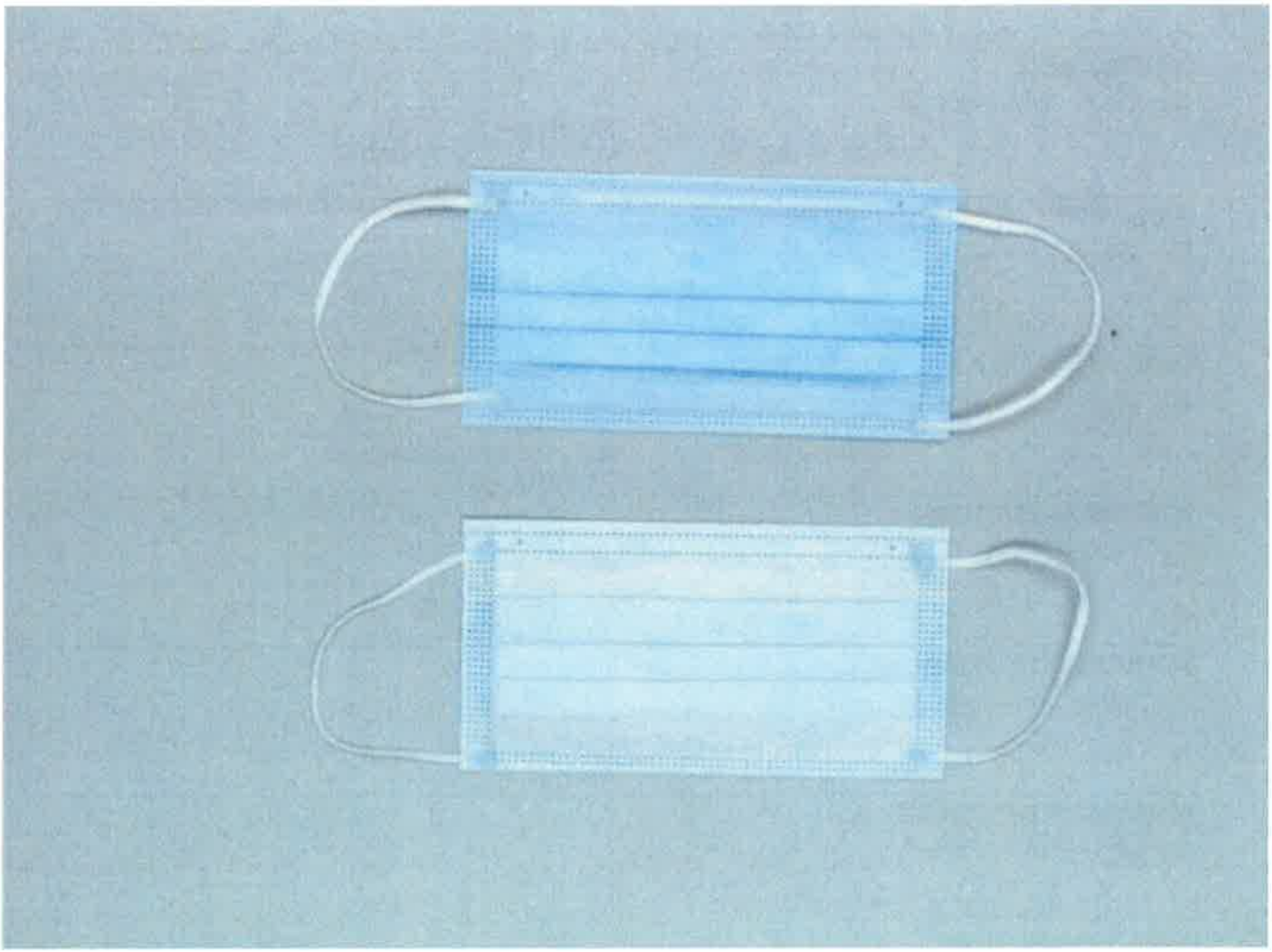
总部：[illegible]
花都实验室：[illegible]

广检集团
GTTC

TEST REPORT

(Electronic version)

No:200109316



广州检验检测认证集团有限公司
检验检测专用章
(GF2)

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旧岭河流为路1号
电话:020-61994598;61994599
电话:020-37721161

TEST REPORT

(Electronic version)

No:200109316

BACTERIAL FILTRATION EFFICIENCY(%)

(YY 0469-2011 ANNEX B, TEST BACTERIA: STAPHYLOCOCCUS AUREUS ATCC 6538, TEST AREA: 40cm^2, FLOW RATE: 28.3L/min, MEAN PARTICLE SIZE: 3.0μm, RESULT OF THE POSITIVE CONTROL: 1.9×10^3 CFU, RESULT OF THE NEGATIVE CONTROL: <1CFU)

		REQUIREMENT
BFE_1	99.5	≥95
BFE_2	99.2	(YY 0469-2011)
BFE_3	99.0	

COLIFORM GROUP

(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY 0469-2011)

TOTAL AMOUNT OF BACTERIAL COLONY(CFU/g)

(GB 15979-2002 ANNEX B)

	REQUIREMENT
<20	≤100 (YY 0469-2011)

TOTAL AMOUNT OF FUNGUS COLONY(CFU/g)

(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY 0469-2011)

PSEUDOMONAS AERUGINOSA

(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY 0469-2011)

STAPHYLOCOCCUS AUREUS

(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY 0469-2011)

HEMOLYTIC STREPTOCOCCUS

(GB 15979-2002 ANNEX B)

	REQUIREMENT
NOT DETECTED	MUST NOT BE DETECTED (YY 0469-2011)

APPEARANCE[3 PIECES]

(YY 0469-2011 5.1)

	REQUIREMENT
PASS	THE APPEARANCE OF THE MASK SHOULD BE NEAT AND INTACT, AND THERE SHOULD BE NO DAMAGE OR STAIN ON THE SURFACE (YY 0469-2011)

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部：广州市番禺区东仁路1号
花都实验室：广州市花都区[illegible]

广检集团 GTTC

TEST REPORT

(Electronic version)

No:200109316

STRUCTURE AND SIZE[3 PIECES]

(YY 0469-2011 5.2)

STRUCTURE: PASS			REQUIREMENT
SPECIFICATION(cm):			AFTER WEARING THE MASK, IT SHOULD BE ABLE TO COVER THE WEARER'S NOSE, MOUTH TO JAW, AND SHOULD CONFORM TO THE DESIGN SIZE AND TOLERANCE. (YY 0469-2011)
	LENGTH	WIDTH	
1#	17.4	9.3	
2#	17.4	9.2	
3#	17.4	9.1	

NOSE CLIP[3 PIECES]

(YY 0469-2011 5.3)

		REQUIREMENT
	PASS	THE PLASTIC NOSE CLIP SHOULD BE ATTACHED TO THE MASK. THE NOSE CLIP LENGTH SHOULD NOT BE LESS THAN 8.0cm. (YY 0469-2011)

MASK STRING[3 PIECES]

(YY 0469-2011 5.4)

		REQUIREMENT
	PASS	MASK STRING SHOULD BE EASY TO WEAR. THE BREAKING STRENGTH AT THE CONNECTION POINT BETWEEN EACH MASK BELT AND THE MASK BODY SHOULD NOT BE LESS THAN 10N. (YY 0469-2011)

RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD

(YY 0469-2011 5.5, SURFACE TENSION OF SYNTHETIC BLOOD:0.042N/m)

		REQUIREMENT
	NO PENETRATION	NO PENETRATION APPEARED ON THE INSIDE OF MASK. (YY 0469-2011)

PARTICLE FILTRATION EFFICIENCY(%)

(YY 0469-2011 5.6.2, AIR FLOW: 30L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m^3, TEMP: 24.0℃, RH: 37.1%)

		REQUIREMENT
	MINIMUM 99.639	≥30 (YY 0469-2011)

FLAME RETARDANT PERFORMANCE(s)

(YY 0469-2011 5.8)

		REQUIREMENT
	1# 0.0	≤5
	2# 0.0	(YY 0469-2011)
	3# 0.0	

广检检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

总部：广州市番禺区
花都实验室：广州市花都区
电话 020-31
电话 020-32

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD
4th Floor, No.1 Building, No.6 Ji'an Road, Tong'an District Xiamen, Fujian, 361100, CHINA

The facility registration and device listing information:

The Owner/Operator Number: 10062942		
Device Listing No.	Product Code	Product Name(s)
D374915	FYF	Caps
D374916	FRL	Bed Sheet
D374917	EYQ	Adult Nursing Pad, Baby Care Mat, Adult Diapers, Baby Diapers, Adult Insert Diapers
D374918	KHA	Face Mask
D374919	FYE	Surgical Gown
D374920	KME	Bed Mattress
D374921	OEA	Isolation Gown
D389717	LYU	Disposable mask
D389718	QKR	Disposable mask

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. ***This attestation does not denote endorsement or approval of the attestation-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 attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.***

Reference Number: 2007US069518-1
Reissue date: Apr.27, 2020

Authorizing Signature
Only used for the US Agent Signature

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

Test Report

(Electronic version)

Verification Code: IDIL-0611-24
Verification Website: www.gttc.net.cn

No:20R005210 Issue Date: 2020-08-13

Applicant: XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO., LTD
Address: 4TH FLOOR, BUILDING 1, NO.6 JI'AN ROAD TONGAN DISTRICT, XIAMEN, CHINA

Information confirmed by applicant:
Disposable surgical mask
Quantity: 80 pieces
Type: MP9017

Standard Adopted:
ASTM F 2100-2019 <Standard Specification for Performance of Materials Used in Medical Face Masks>

Date Received/Date Test Started: 2020-08-04

Conclusion:

Bacterial filtration efficiency (BFE)	M
Differential pressure	M
Resistance to penetration by synthetic blood	M
Flammability	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Zi Shan Guo
ZiShan Guo Senior Engineer

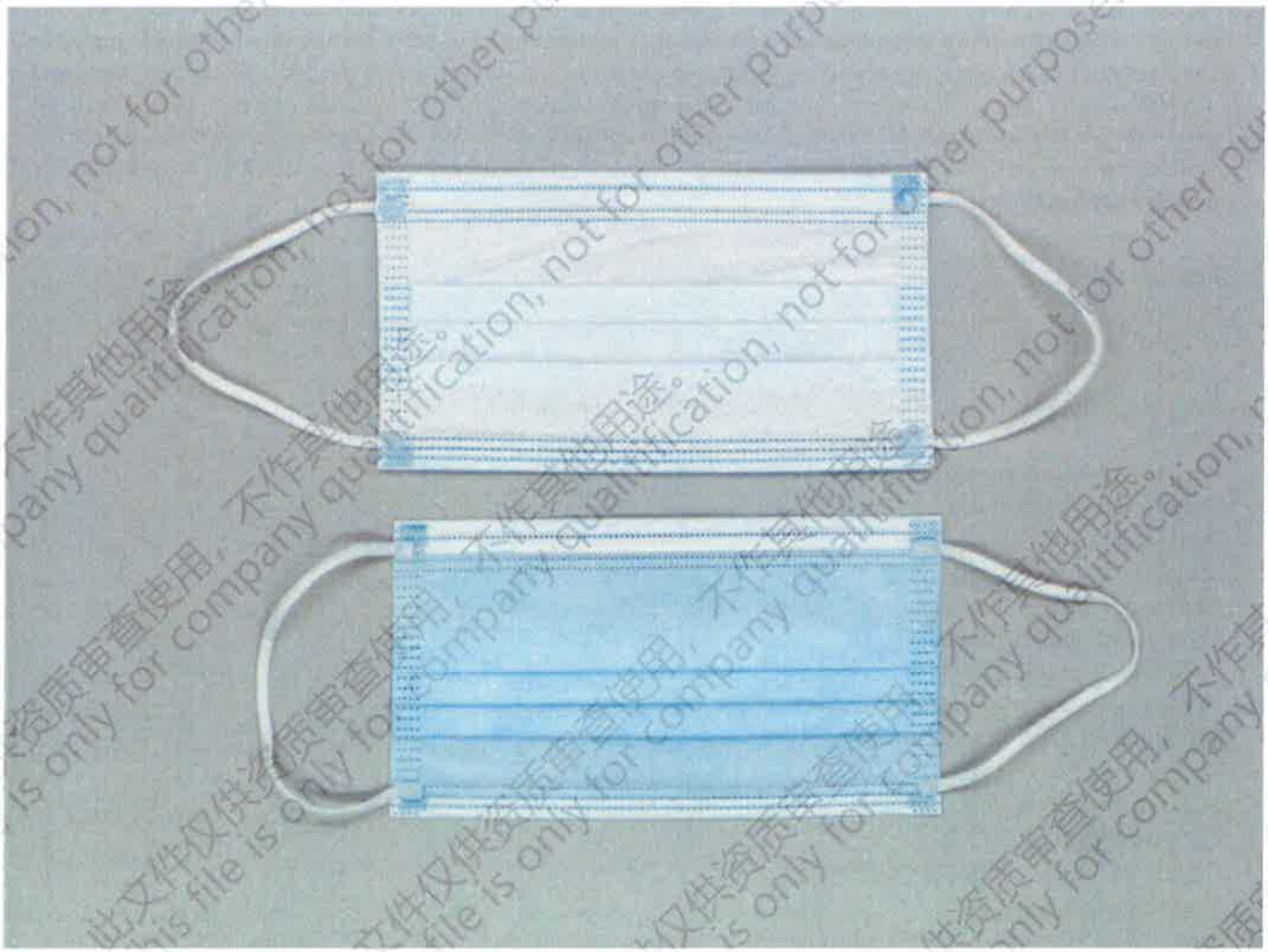
Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

(Electronic version)

No: 20R005210



Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Inspection & Testing services

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

(Electronic version)

No: 20R005210

Bacterial filtration efficiency (BFE)
Test Method: ASTM F 2101-2019

Test principle:
The medical face mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus.The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts.The agar plates from the cascade impactor are incubated for 48 h and counted to determine the number of viable particles collected. The ratio of the upstream counts to the downstream counts collected for the test specimen are calcu lated and reported as a percent bacterial filtration efficiency.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture Medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^5 CFU/ml
Positive control average (C): 1.9×10^3 CFU
Negative monitor count: ＜1 CFU
Test area: 49 cm^2
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Inspection & Testing services

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

(Electronic version)

No: 20R005210

Results:

Sample	T	BFE (%)	Requirement (%)	Performance Level	Conclusion
1	8	99.58	≥98 ASTM F 2100-2019	Level 3	Pass
2	6	99.68			
3	6	99.68			
4	12	99.37			
5	7	99.63			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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电话：020-37721161/66348638

Test Report

(Electronic version)

No: 20R005210

Differential pressure

Test method: EN 14683:2019+AC:2019 Annex C

Test principle:

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:

GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min

Test area: 4.9cm^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

Test location: Top left, Bottom left, Middle, Top right and Bottom right

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Test Report

(Electronic version)

No: 20R005210

Results:

Sample		1	2	3	4	5	Requirement (mmH_2O/cm^2)	Performance Level	Conclusion
Measured value (Pa)	Top left	114	107	110	108	109	<6.0 ASTM F 2100-2019	Level 3	Pass
	Bottom left	118	120	119	114	105			
	Middle	110	116	115	105	110			
	Top right	115	120	120	116	119			
	Bottom right	113	109	113	105	109			
	Average	114	114	115	110	110			
Differential pressure (mmH_2O/cm^2)		2.38	2.38	2.40	2.29	2.29			

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电话：020-37721161/66348638

Test Report

(Electronic version)

No: 20R005210

Resistance to penetration by synthetic blood
Test method: ASTM F1862/F1862M-2017

Test principle:
A volume of synthetic blood is disbursed at a specimen mask by a pneumatically controlled valve from a set distance to simulate the impact (splatter) of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given healthcare scenario. Any evidence of synthetic blood penetration on the inner facing of the medical face mask (side contacting the wearer's face) constitutes a failure. Results are reported as pass/fail. Specimen medical face masks are evaluated at velocities of 450, 500, and 635 cm/s. These correspond to the velocityexiting a small arterial puncture at human blood pressures of 10.7, 16.0, and 21.3 kPa (80, 120, and 160 mmHg). Test results are reported at each velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which medical face mask specimens demonstrate an acceptable quality limit of 4.0.

Test equipment:
Test apparatus for synthetic blood penetration LFY-227
Air compressor
Graduated cylinder
Electronic balance
Targeting plate

The environmental conditions of the laboratory and test condition:
Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

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Test Report

(Electronic version)

No: 20R005210

Results:

Sample	Measured value Pressure 160 mmHg	Requirement (mmHg)	Performance Level	Conclusion
1	pass	≥160 ASTM F 2100-2019	Level 3	Pass
2	pass			
3	pass			
4	pass			
5	pass			
6	pass			
7	pass			
8	pass			
9	pass			
10	pass			
11	pass			
12	pass			
13	pass			
14	pass			
15	pass			
16	pass			
17	pass			
18	pass			
19	pass			
20	pass			
21	pass			
22	pass			
23	pass			
24	pass			
25	pass			
26	pass			
27	pass			
28	pass			
29	pass			
30	pass			
31	pass			
32	pass			
Final result	pass			

Remarks:

An acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.

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Test Report

(Electronic version)

No: 20R005210

Flammability

Test method: 16 CFR Part 1610

Test principle

Each specimen cut from the textile shall be inserted in a frame, brushed if it has a raised-fiber surface, and held in a special apparatus at an angle of 45°. A standardized flame shall be applied to the surface near the lower end of the specimen for 1 second, and the time required for the flame to proceed up the fabric a distance of 127 mm (5 in) shall be recorded. A notation shall be made as to whether the base of a raised-surface textile fabric ignites or fuses.

Test equipment:

Flammability apparatus
Drying oven
Brushing device

The environmental conditions of the laboratory and test condition:

Pretreatment: the specimens shall be dried in the oven for 1 h at 105℃
Type of gas: tetrane

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Test Report

(Electronic version)

No: 20R005210

Results:

Sample	Burning time before washing		Flammability class	Requirement	Performance Level	Conclusion
	Length (Face)	Width (Face)				
1	IBE	IBE	Class 1, Normal Flammability	Class 1, Normal Flammability ASTM F 2100-2019	**Level 3**	**Pass**
2	IBE	IBE				
3	IBE	IBE				
4	IBE	IBE				
5	IBE	IBE				
Average	IBE	IBE				
Final result	IBE					
Flammability characteristic	Melt					

Remarks:
IBE---Ignited, but extinguished.

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———End of Report———

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article:	Product Name: Disposable Surgical Mask Model: MP9017 Lot No.:20200319
Study Number:	1291233-S01
Study Received Date:	21 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~166 mm x ~160 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.7 µm

Trang Truong electronically approved
Study Director Trang Truong

10 Jun 2020 22:53 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.9
2	>99.9
3	>99.9
4	99.9
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.2	50.5
2	5.1	50.4
3	4.9	48.2
4	5.4	53.0
5	5.5	54.0

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{\mathrm{A}}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 May 2020
Phase Inspected by Quality Assurance: Delta P Measurements	20 May 2020
Audit Results Reported to Study Director	27 May 2020
Audit Results Reported to Management	28 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

10 Jun 2020 21:23 (+00:00)
Date and Time

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Latex Particle Challenge GLP Report

Test Article:	Product Name: Disposable Surgical Mask Model: MP9017 Lot No.:20200319
Study Number:	1291232-S01
Study Received Date:	21 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s): QE22125

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	22°C, 23% relative humidity (RH) at 0815; 22°C, 23% RH at 0920
Average Filtration Efficiency:	99.62%
Standard Deviation:	0.151

Trang Truong electronically approved — 27 May 2020 22:12 (+00:00)
Study Director — Trang Truong — Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	45	14,454	99.69
2	40	13,515	99.70
3	41	13,442	99.69
4	44	13,435	99.67
5	87	13,471	99.35

Test Method Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <100 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL was aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The number of particles being delivered to the test article was determined (no medium in air stream) as one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. One-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} x\ 100$$

Where: C = Combined average of the control counts
T = Average test article counts

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 May 2020
Phase Inspected by Quality Assurance: Latex Test	18 May 2020
Audit Results Reported to Study Director	19 May 2020
Audit Results Reported to Management	20 May 2020

Scientists	Title
Suzanne Plympton	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

27 May 2020 13:59 (+00:00)
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Synthetic Blood Penetration Resistance GLP Report

Test Article:	Product Name: Disposable Surgical Mask Model: MP9017 Lot No.:20200319
Study Number:	1291234-S01
Study Received Date:	21 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	20.0°C and 23% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Trang Truong electronically approved
Study Director Trang Truong

26 May 2020 22:35 (+00:00)
Study Completion Date and Time

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be ≤5% (±0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 May 2020
Phase Inspected by Quality Assurance: Penetration Test	14 May 2020
Audit Results Reported to Study Director	19 May 2020
Audit Results Reported to Management	20 May 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Loxane Konesavanh electronically approved
Quality Assurance

22 May 2020 15:16 (+00:00)
Date and Time

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Flammability of Clothing Textiles GLP Report

Test Article:	Product Name: Disposable Surgical Mask Model: MP9017 Lot No.:20200319
Study Number:	1291235-S01
Study Received Date:	21 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met.

Test Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Trang Truong electronically approved
Study Director Trang Truong

28 May 2020 21:58 (+00:00)
Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~⅝ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 May 2020
Phase Inspected by Quality Assurance: Sample Preparation / Conditioning	14 Mar 2020
Audit Results Reported to Study Director	17 Mar 2020
Audit Results Reported to Management	18 Mar 2020

Scientists	Title
Denise Anderson	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Eric Stembridge electronically approved
Quality Assurance

28 May 2020 16:38 (+00:00)
Date and Time

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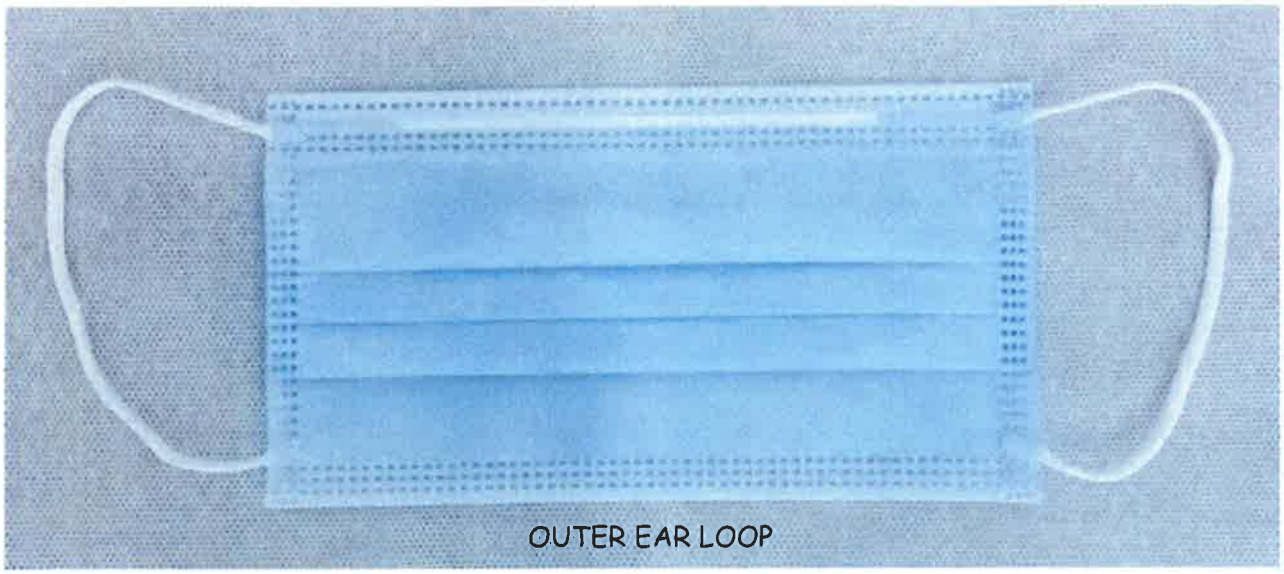

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