DECLARATION OF CONFORMITY

Importer
S.A.S LOCX
6 boulevard des Monts d'Or
69580 Sathonay-Camp

Manufacturing
Suzhou Shiyifang Biotechnology Co., Ltd
Room 302, Building 12, Northwest area, Suzhou nano city, no. 99, Jinjihu Avenue,
Suzhou Industrial Park, Jiangsu Province, China

Designation and Reference
DISPOSABLE NITRILE EXAMINATION GLOVES
REFERENCE : MDG-251

Normes

Norme	Certification Organism	Issued	Report/Certificate Ref.
EN 455-1/2/3	SGS	2021-06-15	Declaration of conformity
EN 374-2:2019	SGS	2020-08-05	QDHL2007007117MD_EN
EN 374-1:2016+A1:2018	SATRA	2021-08-20	2777/16527-02/E01-01
EN 374-5:2016	SATRA	2020-12-23 08-20-21	CHT0305868 / 2049 2777/16527-02/E01-01
EN 16523-1 :2015	SGS	2020-07-16	QDHL2006005936MD_EN
EN 374-4 :2019	SGS SATRA	2020-07-16 2021-08-20 - 2026-04-30	QDHL2006005936MD_EN 2777/16527-02/E01-01
EC 1935/2004 VO (EU) 10/2011	SGS	2021-03-18	SHAHG2103905201
EN 21420:2020	SATRA	2021-08-20 - 2026-04-30	2777/16527-02/E01-01
ISO EN 13485:16	SATRA	2021-08-20 - 2026-04-30	2777/16527-02/E01-01

As well as ISO EN 13485:2016 (LOCX), COMMISSION REGULATION (EC) No 2023/2006.

LOCX, Président , Olivier Euvrard
11/01/2022

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EC Declaration of Conformity

This is a declaration of conformity made According to Art .19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Suzhou SHIYIFANG Biotechnology Co.,Ltd.
Room 302,builiding 12,northwest area,Suzhou nano City,No.99,Jinjihu Avenue,Suzhou Industrial Park,Jiangsu Province,China.
Xin Cui
Tel: +0512-68122111
Email: 83161161@qq.com

whose single Authorized EU-Representative:

Name: StateLab GmbH
Add:Friedrich-Ebert-Straße 7 58642 Iserlohn

Product Name: **Disposable Powder Free Nitrile Gloves**
Product type: **S\M\L\XL**
Product Classification: **Class Ⅰ, Non-sterile, No measuring function (MDR,Annex Ⅷ, Rule 1)**
Basic UDI : **Not available yet**

We hereby declare that above mentioned devices comply with (EU) MDR 2017 /745 and the following harmonized standards.

Executive standard: EN 455-1:2020, EN 455-2:2015,EN 455-3:2015.

meet the provisions of Directive2017/745(EU) which apply to them.

It bears the mark

CE

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of Suzhou SHIYIFANG Biotechnology Co.,Ltd.

Suzhou SHIYIFANG Biotechnology Co.,Ltd.
Room 302,builiding 12,northwest area,Suzhou nano City,No.99,Jinjihu Avenue,Suzhou Industrial Park,Jiangsu Province,China.

Suzhou 2021.6.15
Place, date

Cuixin General manager
Legally binding signature, Function

EU AUTHORIZED REPRESENTATIVE AGREEMENT according to Regulation (EU) 2017/745 for medical devices

No. EU00034

Party A:
甲方：

Name:	Suzhou SHIYIFANG Biotechnology Co.,Ltd
Add:	Room 302,builiding 12,northwest area,Suzhou nano City,No.99,Jinjihu Avenue,Suzhou Industrial Park,Jiangsu Province,China
Tel:	+86 512-68122111
Fax:	+86 512-68122111
Zip Code:	215000

Party B:
乙方：

Name:	StateLab GmbH
Add:	Friedrich-Ebert-Strasse 7 58642 Iserlohn, Germany
Tel:	+49 211 23 98 90 0
Fax:	+49 211 23 98 90 99
Contact Person	Jian wang
Dimdi Code	DE/0000049337
E-mail:	info@statelab.de

Party A hereby appoints Party B as the European Authorized Representative for the Medical Device under the name of Part A with CE mark to provide authorized representative services as required per Regulation (EU) 2017/745 (hereinafter referred to as MDR) where applicable, the appointed product categories are set out in Appendix A.
甲方任命乙方为 CE 医疗器械（甲方作为法定制造商）的授权代表,提供所适用的医疗器械法规 Regulation (EU) 2017/745（以下简称 MDR）中所要求的授权代表服务，委托的产品类别名称、分类、型号清单及预期在欧盟境内销售的国家见附件 A。

Hereafter when reference is made to the EU, this is meant to include the area where MDR has been recognized, including EEA (European Economic Area), Switzerland and Turkey.
以下所提到的 EU，都指的是 MDR 法规认可的区域，包括 EEA（欧洲经济区）、瑞士和土耳其。

Party B shall provide the relevant service as stipulated herein as the authorized representative of Party A. However, Party B is not obliged to bear any product liabilities arising from the entry of Party A's medical products into the EU market, especially from its sale and use. Party A, as legal manufacturer of the device, is the only responsible party. It is

recommended that Party A purchases product liability insurance that is able to cover the volume and risk of products sold within the EU market.
乙方作为甲方的授权代表，提供本协议规定的相关服务。但乙方不承担因甲方医疗产品进入EU 市场，特别是因销售和使用而产生相关的产品责任，对此甲方（作为器械的法定制造商）是唯一对外的责任人。
建议甲方购买产品责任保险，并使该保险足以涵盖其欧盟境内销售的产品量和风险性。

Party B accepts the appointment to be the authorized European Representative for Party A in EU. Both parties enter this agreement as below:
乙方接受甲方任命,为甲方在 EU 市场的 CE 医疗产品授权代表。双方签署下列协议：

Chapter I Obligations and responsibilities of Party A
甲方的责任和义务

1. When placing their devices on the market or putting them into service, Part A shall ensure that they have been designed and manufactured in accordance with the requirements of MDR.

当将其器械投放市场或投入使用时，甲方应确保所有器械根据 MDR 的要求进行设计和生产。

2. Part A shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I of MDR.

制造商应如 MDR 附录 I 第 3 节所述，确立，记录，实施和维护风险管理体系。

3. Part A shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV of MDR, including a PMCF.

甲方应按照载于 MDR 第 61 条附录 XIV 规定的要求进行临床评价，包括 PMCF。

4. Party A, as manufacturer of devices other than custom-made devices, shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III of MDR.

The Commission is empowered to adopt delegated acts in accordance with MDR Article 115 amending, in the light of technical progress, the Annexes II and III of MDR.

甲方作为除定制器械外器械的制造应拟定并更新这些器械的技术文件。该技术文件应允许评定该器械与本法规要求的符合性。该技术文件应包括 MDR 附录 II 和 III 列出的要点。鉴于技术进展和 MDR 附录 II 和附录 III，根据 MDR 第 115 条修订内容，委员会有权批准授权法案。

5. Party A, as manufacturer of custom-made devices, shall draw up, keep up to date and keep available for competent authorities' documentation in accordance with Section 2 of Annex XIII of MDR.

甲方作为定制器械制造商应拟定、更新并向主管机构提供符合 MDR 附录 XIII 第 2 节的文档。

6. Where compliance with the applicable requirements has been demonstrated following the

applicable conformity assessment procedure, Party A (as manufacturers of devices, other than custom-made or investigational devices) shall draw up an EU declaration of conformity in accordance with Article19 of MDR, and affix the CE marking of conformity in accordance with Article 20 of MDR.

若适用的符合性评估流程证明器械符合适用的要求，则甲方作为器械(非定制或研究用器械)制造商应根据 MDR 第 19 条的要求制定欧盟符合性声明，并根据 MDR 第 20 条的要求附上标有符合性的 CE 标识。

7. Part A shall comply with the obligations relating to the UDI system referred to in Article 27 of MDR and with the registration obligations referred to in Articles 29 and 31 of MDR. If Party A places a product on the EU market before obtaining the Registration number of the product approved by the competent authority, then the resulting legal liabilities and economic losses will be borne by Party A and have nothing to do with Party B.

甲方应遵守 MDR 第 27 条中所述的 UDI 系统相关义务，以及 MDR 第 29 和 31 条所述的注册义务。在获得主管部门核准的产品注册码之前，甲方自行将产品投放 EU 市场，引起的法律责任和经济损失均由甲方承担，与乙方无关。

8. Part A shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56 of MDR, available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, Party A shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

Party A with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3) of MDR, ensure that the authorised representative has the necessary documentation permanently available.

甲方应保存技术文件、欧盟符合性声明、适用时还有根据 MDR 第 56 条颁发的相关证书及修订件和补充件的副本，在欧盟符合性声明中所涵盖的最后器械上市后，该文档应至少向主管机构开放 10 年。若为可植入器械，周期应至少为最后器械已投放市场后的 15 年。经主管机构要求，甲方应提供完整的技术文件或总结。

为使授权代表能够完成 MDR 第 11 (3) 条中所述的任务，在欧盟境外注册营业的甲方应确保授权代表有永久可用的必要文档

9. Part A shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or CS by reference to which the conformity of a device is declared shall be adequately taken into account in a timely manner. Party A (as manufacturer of devices, other than investigational devices) shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device.

The quality management system shall cover all parts and elements of Party A's organisation

dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of MDR.

The quality management system shall address at least the following aspects:

甲方应确保采取必要程序，以使批量生产符合本法规的要求。应及时充分考虑器械设计或特性的更改和协调标准或器械符合性所声明的 CS 的更改。甲方作为器械(非研究用器械)制造商应以最有效的及根据风险等级和器械类别的方式确立、记录、实现、维护、不断更新和不断改善一个能确保器械符合本法规规定的质量管理体系。

质量管理体系包括甲方组织处理流程、程序和器械质量的所有部分和要素。它应管理着结构、职责、程序、流程和管理资源，以贯彻所需的原则和行动，以遵守 MDR 的规定。

质量管理体系应至少解决以下方面的问题:

a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

法规符合性战略，包括符合性评估流程的符合性和系统所涵盖的器械的变更管理程序:

(b) identification of applicable general safety and performance requirements and exploration of options to address those requirements;

确定适用的通用安全与性能要求,寻找可选择的解决这些要求的方法

c) responsibility of the management;

管理责任

(d)resource management, including selection and control of suppliers and sub-contractors;

资源管理,包括选择和管理供应商和分包商

(e) risk management as set out in in Section 3 of Annex I of MDR;

MDR 附录 I 第 3 节中规定的风险管理

(f) clinical evaluation in accordance with Article 61 and Annex XIV of MDR, including PMCF;

临床评价,根据 MDR 第 61 条和附录 X I V 的规定,包括 PMCF;

(g)product realisation, including planning, design, development, production and service provision;

产品实现规划,包括规划、设计、研发、生产和服务提供

(h) verification of the UDI assignments made in accordance with Article 27(3) of MDR to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29 of MDR;

根据 MDR 第 27(3)条规定验证所有相关器械的 UDI 分配,确保根据 MDR 第 29 条提供的信息的一致性和有效性;

(i) setting-up, implementation and maintenance of a post-market surveillance system, in

accordance with Article 83 of MDR;

根据 MDR 第 83 条的要求,建立、实施和维护上市后监管体系

(j) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;

与主管机构、公告机构、其他经济运营商、客户和或其他利益相关人沟通

(k) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;

警戒情况下的严重事件和现场安全纠正措施的报告流程

(l) management of corrective and preventive actions and verification of their effectiveness;

纠正措施和预防措施的管理及其有效性的验证

(m)processes for monitoring and measurement of output, data analysis and product improvement.

产品的监督和测量流程,数据分析和产品改进

10. Part A shall implement and keep up to date the post-market surveillance system in accordance with Article 83 of MDR.

甲方应根据 MDR 第 83 条的规定实施并不断更新上市后监管体系

11. Part A shall ensure that the device is accompanied by the information about label and instructions for use set out in Section 23 of Annex I of MDR in an official Union language determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

甲方应确保器械附有 MDR 附录 I 第 23 节规定的有关标签和使用说明书的信息,且信息应采用器械上市国(同时也是成员国)指定的欧盟官方语言编写。标签上的详情应不可拭除、容易识别并且使用者和患者能够清楚理解。

12 Part A who consider or have reason to believe that a device which they have placed on necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the device in question and, where applicable, the authorised representative and importers accordingly.

甲方认为或有理由认定其投放于市场或交付使用的器械未遵照本法规,应立即采取必要纠正措施使器械符合要求,并适时撤回或召回。甲方其应通知所述的器械经销商,并适时通知授权代表和相应进口商。

Where the device presents a serious risk, Part A shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56 of MDR, in particular, of the non-compliance and of any corrective action taken.

如器械出现严重风险,甲方应立即通知各成员国主管机构哪些器械可用,如适用,公告机构根据 MDR 第 56 条为器械颁发证书,特别是未遵守要求及其采取的纠正措施。

13. Part A shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88 of MDR.

甲方应有一套如 MDR 第 87 和 88 条所述,记录和报告不良事件和现场安全的纠正措施系统。

14. Part A shall, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authority of the Member State in which the manufacturer has its registered place of business may require that the manufacturer provide samples of the device free of charge or, where that is impracticable grant access to the device. Part A shall cooperate with a competent authority at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market or put into service.

甲方应根据主管机构要求,由相关成员国用官方欧盟语言确定,提供其一切必要信息和文档以证明器械符合要求。如制造商有其注册的营业地点,成员国主管机构可要求制造商免费提供器械样品。如不可行,则授予其器械访问权。甲方应与主管机构合作,按其要求,采取纠正措施以消除风险。如不可行,则降低其已投放市场或投入使用的器械所导致的风险。

If Party A fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may, in order to ensure the protection of public health and patient safety, take all appropriate measures to prohibit or restrict the device's being made available on its national market, to withdraw the device from that market or to recall it until Party A (as legal manufacturer) cooperates or provides complete and correct information.

If a competent authority considers or has reason to believe that a device has caused damage, it shall, subparagraph to the potentially injured patient or user and, as appropriate, the patient's or user's damage caused to the patient or user, without prejudice to data protection rules and, unless there is an overriding public interest in disclosure, without prejudice to the protection of intellectual property rights.

The competent authority need not comply with the obligation laid down in the third subparagraph ordinarily dealt with in the context of legal proceedings.

若甲方合作失败或提供的信息和文档不完整或不正确,则主管机构为确保保护公众卫生和患者安全,将采取一切必要措施禁止或限制在国内市场采购该器械,从该市场撤回或召回器械直至甲方（作为法定制造商）与主管机构合作,或提供完整的正确的信息。如主管机构认为或有理由认定器械已造成损害,应当根据要求,协助提供有关第一子段的信息和文档,在不影响数据保护规则,除非在披露凌驾性公众利益,且不影响知识产权保护的前提下,给潜在受伤患者或使用者、患者或使用者的所有权继承人、受伤患者或使用者的医疗保险公司或经受伤患者,或使用者影响的其他第三方。主管机构无须遵守第三子段中有关第一子段所述的信息披露一般是按法律程序进行的义务。

15. Where Part A have their devices designed or manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 30(1) of MDR.

如甲方将其器械交由其他法人或自然人设计和制造,则按照 MDR 第 30(1)条,其法人或自然人的身份信息将成为待提交信息的一部分。

16. Natural or legal persons may claim compensation for damage caused by a defective

device in accordance with applicable Union and national law.

Part A shall, in a manner that is proportionate the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law.

自然人或法人可按照适当欧盟和国家法律,要求对由缺陷器械引起损害进行赔偿。根据风险等级、器械类别和企业规模,甲方应采取措施并根据国家法律在不影响更多防护措施的情况下,根据第 85/374/EEC 号指令,按照其潜在责任提供足够财政保障。

17. Party A shall enable the authorised representative to perform the tasks in relation to the devices as specified in the Article 11(3) of MDR.

甲方应允许授权代表实施 MDR 第 11（3）条中与器械有关的任务。

18.Party A shall appoint two persons as the primary contacts who cooperate with Party B and deal with the daily work according to this agreement. One of them is responsible for regulatory compliance according to Article 15(1) of the MDR who possesses the requisite expertise in the field of medical devices and must provide the copies of his diploma and related certificates. Party A shall notify Party B within two working days if there is any change in the contact person of Party A. The contact information of the contacts shall be written in Appendix C.

甲方需指定二人，作为甲、乙双方的联络人，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。其中一人按 MDR 第 15（1）条，是负责法规符合性要求的医疗器械专业人员，须提供其文凭的复印件和相关证书。甲方联络人如有任何变更，甲方应于两个工作日内通知乙方。双方联络人的联系方式记录在本协议的“附件三”。

Chapter II Obligations and responsibilities of Party B

乙方的责任和义务

1. Where Party A acting as the legal manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if Party A designates a sole authorised representative.

当甲方作为器械法定制造商不在欧盟成员国境内时，仅当甲方指定唯一授权代表后器械才能投放于欧盟市场。

2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.

委任应构成授权代表的授权书，只有在授权代表书面许可时，且至少在相同种类的所有器械有效时，才有效。

3. The authorised representative shall perform the tasks specified in the mandate agreed between it and the Part A.

授权代表应执行其和甲方间授权同意的指定任务。授权代表应根据要求向主管机构提供授权书副本。

The authorised representative shall provide a copy of the mandate to the competent authority, upon request. The mandate shall require, and Party A shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:

授权书应要求且甲方应协助授权代表至少执行相关器械的以下任务：

(a) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by Party A;

核实甲方已起草 EU 符合性声明和技术文件，适用时，甲方已实施了适当的符合性评估流程。

(b) keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56 of MDR, at the disposal of competent authorities for the period referred to in Article 10(8) of MDR;

保留一份可用的技术文件,欧盟符合性声明副本,如使用,保留一份包括所有修订和补充的相关证书副本,并按照 MDR 第 56 条,在 MDR 第 10(8)条指定时期,由主管机构签发;

(c) comply with the registration obligations laid down in Article 31 of MDR and verify that Party A has complied with the registration obligations laid down in Articles 27 and 29 of MDR;

遵守第 31 条规定的注册义务,并核定该甲方已遵守 MDR 第 27 条和 29 条规定的注册义务

(d) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

响应主管机构的要求,提供所有必要信息和文档,采用相关成员国确定的欧盟官方语言,证明器械符合要求;

(e)forward to Party A any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

向甲方转达,授权代表具体有其经营样品注册地成员国主管机构的所有要求,或访问器械,并核实主管机构收到样品或可访问器械:

(f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

配合主管机构采取的任何预防或纠正措施以消除或,如不可行,降低由器械导致的风险

(g) immediately inform Party A about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

立即通知甲方来自医护专业人员,患者和使用者与有关指定器械可疑事件的投诉和举报

(h) terminate the mandate if Party A acts contrary to its obligations under this Regulation.

如甲方违反本法规义务,则终止授权书。

4. The mandate referred to in paragraph 3 of this Article shall not delegate the obligations of Party A as manufacturer laid down in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12) of MDR.

本条第 3 段所述指的授权书不包括承担 MDR 第 10(1)、(2)、(3)、(6)、(7)、(9)、(10)、(11)和(12)所规定甲方作为制造商的义务。

5. Without prejudice to paragraph 4 of this Article, where Party A is not established in a Member State and has not complied with the obligations laid down in Article 10 of MDR, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, Party A.

在不影响本条第 4 段的情况下,当甲方不在成员国的境内,且未遵守 MDR 第 10 条规定义务时,授权代表应与甲方一样为缺陷器械承担法律责任,并一样负有共同连带责任。

6. An authorised representative who terminates its mandate on the ground referred to in point (h) of paragraph 3 shall immediately inform the competent authority of the Member State in which it is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

根据第 3 段(h)点所述的理由终止任务的授权代表应立即将任务的终止和原因通知其所在成员国的主管机构,适当时也可通知参与该器械符合性评估的公告机构。

7. Any reference in this Regulation to the competent authority of the Member State in which Party A has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative, designated by Party A referred to in paragraph 1, has its registered place of business.

本法规中对甲方注册营业地的成员国主管机构的任何引用应理解为,根据第 1 段指定在甲方有注册经营地的授权代表的成员国内,对主管机构的参考地。

8.Party B shall appoint two persons as the primary contacts who cooperate with Party A and deal with the daily work according to this agreement. The contact information of the contacts shall be written in Appendix C.

乙方需指定二人，作为甲、乙双方的联络人，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。双方联络人的联系方式记录在本协议的"附件三"。

Chapter III Service Fee

服务费用

Party A shall pay the service fees to Party B separately according to the agreement for the relevant service stipulated in Part A hereof provided by Party B.
就乙方提供本协议 A 部分规定的相关服务，甲方应当按照单独约定支付乙方服务费用。
Provided that Party A requires Party B to provide the service beyond the scope stipulated herein, both parties shall agree relevant fees separately in writing.
如果甲方需要乙方提供超出本协议规定之外的服务，甲乙双方应当对此另行书面约定相关费用。

A. Term and Termination of the Contract
合同的期限及合同的终止

1. Validity of the Agreement
协议有效期
The validity of this agreement is five years after the signing of the agreement between Party A and Party B.
本协议有效期甲方和乙方自协议签订之日起五年有效。
2. During the execution of the agreement, this agreement is 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：
   2.1 The CE certificate is canceled by Party A, or the CE certificate is suspended or withdrawn by the notify body.
   (In the event of any of the above facts, Party A shall take the initiative to cooperate with Party B to do the following after-work, otherwise, it will bear all the liabilities arising from inaction or misconduct:
      i) Brief statement in writing about the reasons why CE Certificate being cancelled, suspended, or withdrawn.
      ii) Written confirmation of whether there are products exporting to EU market under the withdrawn CE Certificate. If no, a written statement is required; if yes, the sales list is required. The evaluation of risks arising, measures and timetable to solve the problem shall be provided in writing.)
   甲方主动注销 CE 证书，或者 CE 证书被发证机构暂停/撤销的。
   (以上事实一旦发生，甲方需主动配合乙方做好以下善后工作，否则将承担由于不作为或者作为不当而产生的所有责任：
      i) 书面简要说明证书被注销、暂停或撤销的原因。
      ii) 书面确认被取消的 CE 证书所有所列产品是否已经有出口 EU 市场。如果没有，请出具书面声明，如果有，请附上出口销售清单，同时请书面评估由此可能产生的风险并陈述甲方解决问题的措施和时间表。）
   2.2 In the event that Party A fails to provide Party B with the qualified CE technical documentation within 30 days after the certificate is obtained or before the self-declaration product is marked with CE, the agreement is terminated automatically. Within 60 days from the date of termination, Party B can continue to perform the duties of the EU Representative on behalf of Party A in order to facilitate Party A's employment of a new EU representative and change of CE certificate. Party B shall inform the Notified Bodies of the termination of the agreement timely.
   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。在本协议失效之日

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。

2.3 Party A doesn't pay off the service fee or doesn't provide a sales list according to this agreement and refuse to explain on the deadline.
甲方在按协议规定的最后期限内没有付清欧盟代表服务费用或没有提供销售清单，又不作解释的。

3. After the termination of the agreement, Party B should forward to Party A any complaints or reports from healthcare professionals, patients or users about suspected incidents related to the device for which Party B had been designated as authorised representative.
协议终止后，乙方应当将任何来自医疗机构、病人或用户的任何与乙方曾经被指派未欧盟授权代表的产品有关的疑似事故的投诉或报告转告给甲方。
After the termination of the agreement, Party A shall not indicate Party B as authorised representative in any information supplied by Party A (as legal manufacturer), including any promotional material.
协议终止后，甲方不能在任何甲方作为制造商应提供的信息（包括任何促销材料）中指明乙方作为欧盟授权代表。

B. Miscellaneous
其他事项

1. Governing Law /Arbitration
适用法律/仲裁
All disputes between the parties arising in connection with this contract or the execution of this contract, including disputes concerning the validity of this contract and this arbitration clause shall be finally settled in accordance with the Arbitration Rules of the Chinese International Economic Commerce Arbitration commission (CIETAC) where the arbitration process is to execute of the CIETAC-location in Beijing without recourse to the ordinary courts of law. Upon request an incoming arbitral award can be declared enforceable by a national court The place of arbitration is Beijing, Republic of China. An appeal against the arbitral award is not possible. The arbitral award shall also decide about the costs of the proceedings including the costs of the arbitrators. The arbitral tribunal consists of three arbitrators. The substantive law of People's Republic of China is exclusively applicable to the dispute. The language of the arbitral proceedings is Chinese.
所有与本协议相关的或者就本协议有效性（包括本仲裁条款）产生的一切争议和纠纷应当根据位于北京的中国国际经济贸易仲裁委员会的仲裁规则予以解决，由此排除普通法院对之的管辖，仲裁裁决可通过向有管辖权的法院提出申请而得以强制执行。仲裁地为北京。该裁决为终局决定，不能上诉。仲裁裁决中应当对仲裁费用做出规定。仲裁庭将由三名仲裁员组成。争议适用中华人民共和国法律。仲裁语言为中文。

2. Written Form Clause
书面形式
Amendments to this Contract shall only be valid when given in writing. The requirement of form may only be waived in writing. Verbal collateral agreements or modifications are not valid.

本意向协议的任何更改与补充均需以书面形式进行。这一规定同样适用于本条款（关于书面形式）的修改。口头协议和口头修改无效。

3. Contract Language
合同语言
This agreement exists in English and Chinese language. The English version is solely for information purposes. The Parties agree that the Chinese version of this agreement alone shall prevail with legally binding effect.
本协议为中文和英文的对照版本 英文只是起翻译作用，本协议内容以中文为准

4. Severance clause
可分割性条款
In the event that the terms of this Agreement, or their supplements, are invalid now or in the future, the other parts are not affected, and the same also applies to the absence of the agreement. However, both parties to the agreement made it clear that the above severance clause is intended to ensure that the rest of the contract will not be affected as a whole by the ineffectiveness of the contract part. In case of invalid clause and missing part, both parties to the agreement shall, within the scope permitted by the law, reach the common expectation as the standard closest to the original contract and reach an effective supplementary provision to replace the invalid clause or fill in the missing part of the agreement.
如若本协议中的条款或者其补充于现在或者将来无效，其他部分不受其影响，该规定同样也适用于协议内容缺失的情形。但协议双方明确表示，上述可分割性条款是为了确实保证合同其它部分不因合同部分无效而整体无效受到影响。就无效条款和缺失部分，协议双方应当在法律允许的范围内本着最接近原有合同目的，最能达到共同预期为标准，达成有效的补充规定，以替代该无效条款或者填补协议内容的缺失。

5. The rights and obligations as stipulated herein are limited to the products listed in one CE certificate obtained by Party A. If Party A obtains multiple CE certificates, Party A and Party B shall enter into an agreement separately according to the actual number of the certificates.
本协议所规定的权利和义务，仅限于甲方取得的一份 CE 证书列明的产品，若甲方取得多份 CE 证书的，甲、乙双方需按证书的实际份数分别签订协议。

6. Appendix A List of products applying for CE mark
附件 A《申请 CE 标识的产品列表:》
Appendix B Table of contents for the Technical Documentation Submitted to European Representative
附件 B《提交欧盟代表的技术文档目录》
Appendix C Contact Information
附件 C《联系人信息》
Appendix D Conditions, Time, Procedures and Necessary Files of Application for Registration of CE Product in Germany and Update, Withdrawal and Invalidation of Registered Product
附件 D《CE 产品德国申请注册的条件、时间、程序及所需提交的文档和已注册产品的更新、撤销与失效》

Appendix E Management procedure of the sales list of CE products exporting to EU market
附件 E《CE 产品出口欧盟市场销售清单管理方法》
Appendix F Charging Standard of Change and Registration in Germany for CE Product
以上五个附件与本协议具有同等效力。

7. In addition to this agreement, neither Party A nor Party B shall be given any other rights and obligations.
除本协议外，甲、乙双方不被赋予其他权利和义务。

8. In view of the full implementation of the MDR regulations, the competent authorities will have further explanations and implementation measures, so Party B can make necessary amendments and supplements to this agreement.
鉴于 MDR 法规的全面实施， 主管当局会有进一步的解释和实施措施，故乙方可对本协议作必要之修订和补充。

9. Documents and regulations that are referenced in this agreement:
本协议参考、引用之文献、法规：
   1） REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
   欧洲医疗器械法规 REGULATION EU 2017/745, 05.04.2017
   2） Vigilance System Guidance (MDD 2.12-1 REV.8 January 2013)
   《警戒系统指南》（医疗器械指令 2.12-1 REV.8 January 2013）
   3） 《GUIDELINE FOR AUTHORIZED REPRESENTATIVES<MEDDEV 2.5/10>》 (January 2012)
   4） 德国医疗器械法（The Act on Medical device）
   5） 德国医疗器械安全计划条例
   Verordnung über die Erfassung, Bewertung und Abwehr von Risiken bei Medizinprodukten (Medizinprodukte- Sicherheitsplanverordnung - MPSV)

Note: during the validity period of the agreement, any change involving the revision/update of the above regulations shall be carried out in accordance with the new version. Party A and Party B shall not sign a new agreement.
备注：在协议有效期内，凡涉及以上法规修正/升级等变更的，按照新颁布的版本内容执行，甲、乙双方不在签订新的协议。

Part A:
甲方：

Cuixin
(法人代表签名 / Signature
公司盖章/ Stamp)

2021.6.16
(日期 / Date)

Party B: StateLab GmbH
乙方：StateLab GmbH
StateLab GmbH
Friedrich-Ebert-Straße 7, 58642 Iserlohn
Tel.: +49 2374 ... 211 23 98 90 99
Email: info@statelab.de www.statelab.de
Ust.-ID: DE333317392

(法人代表签名 / Signature
公司盖章/ Stamp)

16.06.2021
(日期 / Date)

Appendix A - 附件 A

List of products applying for CE mark:
申请 CE 标识的产品列表:

序号 No.	CE 证书号码（如适用） CE certification #（if applicable）	CE 证书有效期 (如适用) CE certification valid date (if applicable)	产品名称 Product name	型号 Model	UMDNS /EDMS	产品分类 Device Class (e.g.: I, Is, Im, IIa, IIb, III, List A, List B, others)	销售国家列表 Sales country list
1	N/A	N/A	Disposable Powder Free Nitrile Gloves	S\M\L\XL	11882	Class Ⅰ	EU

Appendix B - 附件 B

Contents for the Technical Documentation Submitted to European Representative according to MDR Annex II and III
根据 MDR 附录 II 和 III 需要提交欧盟代表的技术文件的内容

1. 器械描述和规范（根据 MDR 附录 II，1.1 条）
   a) 产品名称、描述、预期用途
   b) 产品识别：Basic UDI-DI 或其他识别信息
   c) 预期患者人群、医疗条件
   d) 工作原理
   e) 是否医疗器械以及分类
   f) 创新特性
   g) 附件信息
   h) 规格型号描述
   i) 关键功能要素
   j) 原材料信息
   k) 技术规范
   l) 上一代或类似器械的参考
2. 制造商需要提供的信息：如，标签、说明书样稿。
3. 设计和制造信息：有助于理解器械设计阶段的信息、制造过程描述、场地
4. 通用安全和性能要求
5. 收益-风险分析及风险管理：风险管理计划及报告
6. 产品验证和确认
   a) 临床前研究：测试报告、模拟试验；有关测试设计、完整的测试或研究方案，数据分析方法，以及相关数据摘要和测试结论，如：生物相容性评价、电气安全、EMC、软件验证和确认、稳定性研究、性能和安全性评价。
   b) 临床评价计划、报告
   c) 与药物、人源、动物源、可吸收、含 CMR/内分泌干扰物、无菌、测量功能、器械连接等有关的特别考量。
7. 上市后监督有关的文件：
   a) PMS 计划
   b) PMS 报告和/或 PSUR
   c) PMCF 计划、报告
   d) 安全和临床性能总结

The latest version of the technical documentation shall be provided in writing or in electronic form to the European representative at any time if necessary;
技术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。

Appendix C - 附件 C

Part A Contact Information
甲方联系人信息

Name 联系人姓名	Title 职务	Landline 座机	Mobile Phone 手机	Email 邮箱
Cui Xin	General Manager	0512-68122111	13328033666	83161161@qq.com
Yang Mingyi	Dept. of Quality	0512-68122111	18506120410	1129022717@qq.com

Note: Please provide the information of two contacts, including landline, mobile phone and email, so that we can transfer the relevant information of the European Union to your company in a timely manner when needed. One of them is responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices and must provide the copies of his diploma and related certificates.

注：请提供两名联系人信息包括座机、手机及邮箱，以便我们在需要的时候，可以及时的将欧盟的相关信息传递给贵司。其中一人须是负责法规符合性要求的医疗器械专业人员，并提供其文凭的复印件和相关证书。

Part B Contact Information
乙方联系人信息

Name 联系人姓名	Title 职务	Landline 座机	Mobile Phone 手机	Email 邮箱
Jian Wang	Managing Director	0049 211 23 98 90 0	0049 172 5666666	info@statelab.de
Xiong Wu	Registration Engineer	0049 211 23 98 90 0	0049 173 9263305	xiong.wu@statelab.de

Please inform of any change of contact information promptly.
联系人如果发生变化，请在第一时间知会。

Appendix D - 附件 D

Conditions, Time, Procedures and Necessary Files of Application for Registration of CE Product in Germany and Update, Withdrawal and Invalidation of Registered Product
《CE 产品德国申请注册的条件、时间、程序及所需提交的文档和已注册产品的更新、撤销与失效》

一、 Conditions of Application for Registration of CE Products
CE 产品申请注册的条件：

Party A has obtained the CE certificate, or "Self Declaration" has been made for Class I products.
甲方产品已经取得 CE 证书，或者一类产品已进行自我声明。

二、CE product application registration time:
CE 产品申请注册的时间：
The pre-market approval in EEA, Switzerland or Turkey takes at least 30 days.
产品拟进入 EEA 或瑞士、土耳其市场前至少 30 天。

三、Procedures of Application for Registration of CE Products
CE 产品申请注册的程序：

1、Party A shall notify Party B of the application for registration of products in oral or written form.
甲方向乙方以口头或书面形式提出产品注册申请。

2、Party A shall submit the application form for registration of product and the technical documentation to Party B. The application form for registration is provided by Party B and completed by Party A. Party B shall also provide the preparation requirements for technical files to Party A for reference.
甲方向乙方提交产品注册申请表和技术文档，其中注册申请表由乙方提供、甲方填写；乙方还会提供技术文档的编排要求等供甲方准备文档时参考。

3、The technical files submitted by Party A shall be supplemented, corrected and amended if the contents are missing and incorrect, or if the format does not meet the requirements. If there are too many missing or incorrect, Party A shall pay Party B the agreed processing expenses.
甲方提交的技术文档，如有内容缺失、错误，编排格式有不符要求的，须进行文档的补充、纠正及修正；若缺失、错误过多，甲方须向乙方支付约定的处理费用。

4、Party A shall pay the registration fee to party B,Party A obtains the product registration number.
甲方支付乙方双方约定的注册费用，甲方获得产品注册号码。

四、Necessary Files of Application for Registration of CE Products (English electronic copy)
CE 产品申请注册所需提交的文档（英文电子版本）

1、Scanning copy of the latest certificate of CE product (not required for Self-Declaration products);
最新的 CE 产品证书扫描件（自我声明产品不需要）；

2、 CE technical documentation: English electronic copy, all items required in Part A (especially Declaration of Conformity, description of product, label, instructions for use, etc.), risk management, and clinical data required in Part B, which may not be provided if regulations like MDD/IVDD and appendices clearly indicate that the clinical data of the product are not required);
CE 技术文件：英文、电子版本，文件的 A 部分都要（尤其是符合性声明，产品说明，标签，说明书等），B 部分的风险管理和临床数据(除非 MDR，IVDD 等法规及附录明确不需要临床数据的产品可以不提供);

3、 Sample photographs/pictures of CE marked products (not required if they are available in the technical documentation)
CE 产品实样照片/图片（如果技术文件中有，则不必提供）；

4、 Photographs/pictures of labels fixed on the CE marked products exporting to European Union (not required if they are available in the technical documentation)
贴在出口到欧盟 CE 产品上标签的照片/图片（如果技术文件中有，则不必提供）；

5、Application form for registration (provided by Party B) completed by Party A.
甲方填写的由乙方提供的注册申请表。

6、 Other documents required by the German authorities.
德国主管当局要求提交的其他文档。

五、Renewal registration of CE marked products
CE 已注册产品的更新：
If there are any changes of CE certificates or declaration of conformity of CE registered products, update of registration of CE products is required. Party A shall only submit new CE certificate, new declaration of conformity and application form for registration to Party B, so that the product can be registered and updated.
CE 已注册产品的 CE 证书或其符合性声明发生变更的，需要办理 CE 产品的注册更新。甲方只须向乙方提交产品新的 CE 证书、新的符合性声明以及注册申请表，即能办理产品的注册更新。

六、Withdrawal and invalidation of registered product:
CE 已注册产品的撤销与失效：

1. When the relevant CE certificate is withdrawn, closed or recalled by the certification authority, registration of the product is withdrawn.
相关 CE 证书被发证机构撤销、关闭或收回时，产品注册撤销。
2. Registration of the product is withdrawn by the German authority.
产品注册被德国主管当局撤销。
3. When the EU Authorized Representative Agreement signed by the two parties is terminated, registration of the product is withdrawn.
甲乙双方签署的《EU Authorized Representative Agreement》中止时，产品注册撤销。
4. If the CE certificate exceeds the validity period, registration of the product is invalid.
CE 证书超过有效期的，产品注册失效。
5. When the EU Authorized Representative Agreement signed by the two parties is not renewed after expiration, registration of the product is invalid.
甲乙双方签署的《EU Authorized Representative Agreement》 到期未能续签的，产品注册失效。
6. When other conditions related to withdrawal and invalidation of registration occur, registration of the product is withdrawn or invalid.
其他产品注册的撤销与失效的条件发生时，产品注册撤销或失效。

Websites of competent authorities responsible for registration of CE medical device in

Germany:

附：德国负责 CE 医疗器械产品登记等工作的主管当局网站：

1） www.bfarm.de (German Ministry of Health)
www.bfarm.de(德国卫生部网址)

2） www.dimdi.de (Website of Data of Medical Device CE Registration in Germany)
www.dimdi.de(德国 CE 标志医疗器械产品注册数据中心网址)

Appendix E - 附件 E

Management procedure of the sales list of CE products exporting to EU market
《CE 产品出口欧盟市场销售清单管理方法》

一、Basis for the establishment of the procedure
本办法制定的依据：
The management procedure is established based on the provision on the responsibilities of the European Representative in *Vigilance System Guidance* "3.1 European Representative: after receiving the incident report, the European Representative shall contact the manufacturer and the competent authorities promptly, give the customer's complaint and incident report to the manufacturer, and be responsible for the protection of the product sales record" and the relevant contents of the EU Authorized Representative Agreement signed by the two parties.
《警戒系统指南》中，有关欧盟代表职责的规定："3.1 欧洲授权代表：收到事故报告后应及时与制造商及主管当局联系，及时把客户的投诉和事故报告传递给制造商，并负责保护产品销售记录。"的内容，以及甲、乙双方签定的《EU Authorized Representative Agreement》相关内容，是制定本管理办法的依据和基础。

二、Measures managed in the procedure
本办法管理的方法：
In addition to the relevant contents of the sales list as stipulated in Clause 6 of PARTY A in EU Authorized Representative Agreement, Party A and Party B specially agree on the following rules for operation which the two parties shall follow:
除了协议《EU Authorized Representative Agreement》中 PARTY A 部分第 6 条规定的有关销售清单的相关内容以外，甲、乙双方特约定下列操作细则，双方共同遵照执行：

1、 It is tentatively determined that Party A shall regularly submit the sales list of products exporting to the European market to Party B by email every three months. The specific time is as follows: the export list from January 1st to March 31th of the present year is submitted before the last working day of April; the export list from April 1st to June 30th of the present year is submitted before the last working day of July; the export list from July 1st to September 30th of the present year is submitted before the last working day of October; the export list from October 1st to December 31st of the previous year is submitted before the last working day of January.
暂定为甲方每季度定期向乙方，用电子邮件方式提交出口欧盟市场的销售清单；具体时间为：每年 4 月的最后一个工作日前，提交本年度 1 月 1 号至 3 月 31 号的出口清单；每年 7 月的最后一个工作日前，提交本年度 4 月 1 号至 6 月 30 号的出口清单；每年 10 月的最后一个工作日前，提交本年度 7 月 1 号至 9 月 30 号的出口清单；每年 1 月的最后一个工作日前，提交上年度 10 月 1 号至 12 月 31 号的出口清单。

2. If there is no product exporting to the EU market within the prescribed period of time manufactured by Party A, a zero declaration report is also needed to be submitted to Party B.
如果甲方在上述规定的时间段里，没有任何产品出口欧盟市场的，也需要向乙方提交零申报报告。

3. Party A shall be responsible for the authenticity and accuracy of the declaration data. If

any omissions, delays, concealment and other issues occur in the declaration above, Party A shall be responsible for the consequences arising therefrom.
甲方须对申报数据的真实、准确负责。如果上述申报发生漏报、迟报、瞒报等问题的，应有甲方负责由此而产生的后果。

4. Party B shall be responsible for the confidentiality and safekeeping of the contents of the declaration of Party A, as well as the timely information delivery to the competent authorities of the European Union.
乙方对甲方的申报内容负有保密和保管的责任，以及向欧盟各主管当局如实、及时传递的义务。

5. As for the declaration above, Party A shall submit the file with the signature to Party B, and Party B shall issue a receipt to Party A after receiving it.
上述申报，甲方需签章递交给乙方；乙方收到申报后，须向甲方出具回执。

三、Format of the appendix to the procedure:
本办法附件的格式:
Appendix E.1. Template of Sales List (Format for reference only):
附件 E.1、销售清单样本：（格式仅供参考）：

序号 No.	产品名称 Product Name	产品注册码 Registration Number	销售国家列表 Sales Country List	出口日期 Export Date	批次号 Batch No. or SN	数量 Quantity	进口商 Importer
1							
2							

附件 E.2 零申报声明格式：（仅供参考）
Appendix E.2 Zero Declaration (Format for reference only):
《DECLARATION》
致：StateLab GmbH（乙方）：兹有_____公司（甲方），在本期：____年 1 月 1 号至 3 月 31 号(或者是**年 4 月 1 号至 6 月 30 号...)，有关出口欧盟的销售清单内容，没有需要申报的数据，特此声明。

甲方代表签章 日期：

To: StateLab GmbH (Party B)
We_____(Party A) declare that there are no any export data in E.U. to submit during the period from January.1 to March.30,20**(or from April.1 to June. 30, 20**...).

Signature:
Date

End of the page
本页以下无内容.

Issued to:

Suzhou SHIYIFANG Biotechnology Co Ltd
Room 302 Building 12, Nortwest Area
Suzhou Nano City, No.99 Jinjihu Avenue
Suzhou Industrial Park
Jiangsu Province
215000
China

Notified Body: 2777

SATRA customer number: P21098

EU Type-Examination Certificate

Certificate number: 2777/16527-01/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:

SYF-ST01

Description:

Disposable Powder Free Nitrile Gloves

Colour: Blue

Sizes:

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

Classification:

EN ISO 374-1:2016+A1:2018 /Type C	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	5	-23.4
30% Hydrogen Peroxide (P)	1	35.8
37% Formaldehyde (T)	5	13.6

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied**:**
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0307836/2104, CHT0305868/2049, CHM0308176/2105/JH/A, CHM0308176/2105/JH/B

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 30/04/2021
Date of issue: 30/04/2021
Expiry date: 30/04/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Suzhou SHIYIFANG Biotechnology Co.,Ltd.
Room 302,buiiding 12,
Northwest area,
Suzhou nano City,
No.99,Jinjihu Avenue,
Suzhou Industrial Park,
Jiangsu Province,
China

SATRA reference: CHT0307836 /2104

Your reference: SYF-ST01

Date of report: 19 February 2021

Samples received: 28 January 2021

Date(s) work carried out: 4-10 February 2021

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak on Disposable Powder Free Nitrile Gloves referenced as SYF-ST01, Colour: Blue, Size: S-6; M-7; L-8; XL-9

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Gladys He
Position: Technologist
Department: China Testing

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as SYF-ST01, Colour: Blue, Size: S-6; M-7; L-8; XL-9 were received by SATRA on 28 January 2021 for testing in accordance with EN ISO 21420: 2020 and EN ISO 374-2: 2019.

SAMPLE SUBMITTED

Samples described as Disposable Powder Free Nitrile Gloves referenced as SYF-ST01, Colour: Blue

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 374-2: 2019 Clause 7.2 – Air leak
EN ISO 374-2: 2019 Clause 7.3 – Water leak
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves referenced as SYF-ST01, Colour: Blue, Size: S-6; M-7; L-8; XL-9 were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN ISO 374-2: 2019 Clause 7.2 – Pass
EN ISO 374-2: 2019 Clause 7.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMFa

Detailed results are included on the following page(s)

Testing

Testing was carried out in accordance with EN ISO 21420:2020 and EN ISO 374-2: 2019

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	**1**	**2**	**3**	**4**	**5**
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 2 – Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

Table 3 – EN ISO 21420:2020 Test Results

Clause / Test	Requirement	Test Results	UoM (See note ♣)	Result
5.1 Glove length, comfort and fit	N/A	Size / Length /mm: 1 / 2 / 3 6: 240 / 240 / 240 Comfortable on fit 7: 235 / 235 / 236 Comfortable on fit 8: 240 / 235 / 240 Comfortable on fit 9: 250 / 250 / 250 Comfortable on fit	± 1.10 mm	N/A
5.2 Dexterity	See table 1	Size / Minimum pin diameter / mm 6: 5.0 7: 5.0 8: 5.0 9: 5.0	N/A	Level 5

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results		UoM (See note ♣)	Result
7.2 Air leak test	Total air pressure used	2.9 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A210130007001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder Free Nitrile Gloves referenced as SYF-ST01, Color: Blue	Gloves	-

pH Value - EN ISO 21420:2020

Test Method I : With reference to EN ISO 4045:2018, analyzed by pH meter.
Test Method II: With reference to ISO 3071:2020, analyzed by pH meter.

Requirement:	3.5-9.5

-	Unit	Result
Test Item(s)	-	**I001**
Test Method	-	**II**
Parameter	-	-
pH Value of Extracting Solution	-	5.48
Temp. of Aqueous Extract	deg. C	25.0
pH Value of Aqueous Extract	-	6.6
Difference Figure	-	-
Conclusion	-	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature
Remark: Result(s) was (were) reported the average value from two trials.

Polycyclic Aromatic Hydrocarbons (PAHs) Content - EN ISO 21420:2020

Test Method : With reference to test method PD CEN ISO/TS 16190:2013

Maximum Allowable Limit:	**Each of all listed PAHs: 1.0 mg/kg**

Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hyrdocarbons is summarized in table of Appendix.

APPENDIX

List of Polynuclear Aromatic Hydrocarbons:

No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

Test Method: With reference to EN 16778:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		I001	
Dimethylformamide(DMFA)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key: ND = Not detected (<Detection Limit) Detection Limit (mg/kg) : 5
mg/kg = milligram per kilogram = ppm = part per million

***** End of Report *****

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.

1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.

1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and

1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and

1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and

1.5.4 "PRC" means the People's Republic of China.

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2 FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3 INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.

3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4 SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5 LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
5.2.2 fraud or fraudulent misrepresentation; or
5.2.3 any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6 MISCELLANEOUS

6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7 CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms and conditions and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8 AMENDMENT

8.1 No amendment to a Contract shall be effective unless it is in writing, expressly stated to amend the Contract and signed by an authorised signatory of both Parties.

9 DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.

9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

10 PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

13.4.1 hold the Goods as SATRA's bailee;

13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause13 shall remain in effect.

14 PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and

16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or

16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satrafe.com

Customer details: Suzhou SHIYIFANG Biotechnology Co.,Ltd.
Room 302,buiiding 12,
northwest area,
Suzhou nano City,
No.99,Jinjihu Avenue,
Suzhou Industrial Park,
Jiangsu Province,
China

SATRA reference: CHT0305868 /2049

Your reference: Nitrile Gloves

Date of report: 23 December 2020

Samples received: 4 December 2020

Date(s) work carried out: 8-18 December 2020

TECHNICAL REPORT

Subject: EN ISO 374-5: 2016 viruses test on Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M

Report signed by: Adam Zhang
Position: Technologist
Department: China testing

Adam Zhang

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M were received by SATRA on 04 December 2020 for testing in accordance with EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M

TESTING REQUESTED

EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M were found to achieve the following result:

EN ISO 374-5: 2016 Clause 5.3 – Pass

Detailed results are included on the following page(s)

Signed: Adam Zhang
Technologist
China Testing

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 20R007218. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

Table 1 – Resistance to penetration by blood-borne pathogens results

Sample description:	Disposable Powder Free Nitrile Gloves, Colour: Blue, Size:7M					
Test method	**Specimen**	**Step 1 (0 kPa, 5 min)**	**Step 2 (14 kPa, 1min)**	**Step 3 (0kPa, 4min)**	**Titre of phage Phi-X174 (PFU /mL)**	**Comment**
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

***** End of Report *****

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.

1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.

1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and

1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and

1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and

1.5.4 "PRC" means the People's Republic of China.

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2 FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3 INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.

3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4 SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5 LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
5.2.2 fraud or fraudulent misrepresentation; or
5.2.3 any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6 MISCELLANEOUS

6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7 CONFIDENTIALITY

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9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.

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10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.

Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12 DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

13.2.2 in all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

13.4.1 hold the Goods as SATRA's bailee;

13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause13 shall remain in effect.

14 PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and

16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,

then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or

16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

Client name	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Client address	:	ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO. 99, JINJIHU AVENUE, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, CHINA
Sample Description	:	MEDICAL NITRILE INSPECTION GLOVES
Lot No.	:	20200610001
Lot Size	:	100000
Sample Quantity	:	400PCS
Manufacturer	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Manufacturer Date	:	JUN.10,2020
Appearance	:	BLUE SMOOTH FINGER HEMP HALOGEN FREE GLOVES
Storage Condition	:	ROOM TEMPERATURE

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	JUL.17,2020
Test Performing Date	:	JUL.17,2020 TO AUG.05,2020
Test Performed	:	SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Result(s)	:	FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

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QDHL2007007117MD

Jessica Gao
Approved Signatory

QD 7389263

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Test Conducted:

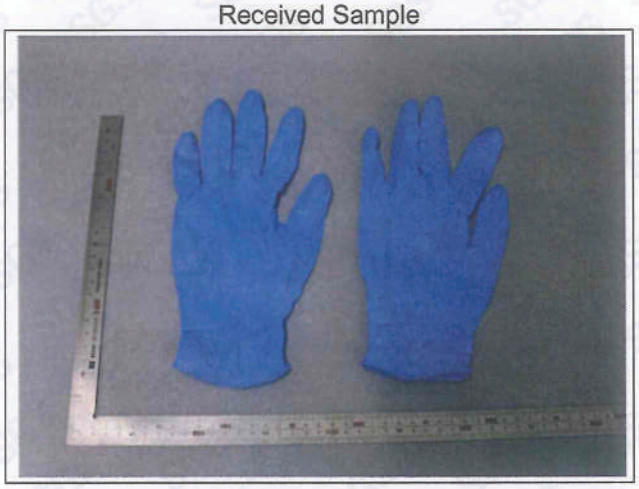
Test Items	Unit	Test Method	Test Result	
Air leak test	/	EN ISO 374-2: 2019	Sample 1	No bubbles escape
			Sample 2	No bubbles escape
			Sample 3	No bubbles escape
			Sample 4	No bubbles escape
Water leak test	/	EN ISO 374-2: 2019	Sample 1	No leakage
			Sample 2	No leakage
			Sample 3	No leakage
			Sample 4	No leakage

Remark:

All tests were carried out by external laboratory assessed as competent (Jiangsu Guojian Testing Technology Co., Ltd, CMA No. 161019130764).

Sample Photo:

Received Sample



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End of Report

Client name	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Client address	:	ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO. 99, JINJIHU AVENUE, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, CHINA
Sample Description	:	MEDICAL NITRILE INSPECTION GLOVES
Lot No.	:	20200610001
Lot Size	:	100000
Sample Quantity	:	400PCS
Manufacturer	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Manufacturer Date	:	JUN.10,2020
Appearance	:	BLUE SMOOTH FINGER HEMP HALOGEN FREE GLOVES
Storage Condition	:	ROOM TEMPERATURE

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	JUN.23,2020
Test Performing Date	:	JUN.23,2020 TO JUL.16,2020
Test Requested	:	SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Result(s)	:	FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S)

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

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Co., Ltd.

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QDHL2006005936MD

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Test Conducted:

Test Items	Unit	Test Method	Test Result			
Resistance to degradation by chemicals	-	EN ISO 374-4: 2019	Formaldehyde 37%	DR_1:32.8% DR_2:31.0% DR_3:29.4% DR:31.1% SD:1.70 There was no obvious change in the physical appearance of the material after chemical exposure		
			Hydrogen peroxide 30%	DR_1:57.0% DR_2:57.4% DR_3:58.7% DR:57.7% SD:0.89 There was no obvious change in the physical appearance of the material after chemical exposure		
			Sodium hydroxide 40%	DR_1: -27.8% DR_2: -27.5% DR_3: -33.5% DR: -29.6% SD:3.38 There was no obvious change in the physical appearance of the material after chemical exposure		
Permeation by liquid chemical	min	EN ISO 16523-1: 2015	Formaldehyde 37%	> 480	Level: 6	Refer To appendix 1
			Hydrogen peroxide 30%	> 480	Level: 6	Refer To appendix 1
			Sodium hydroxide 40%	> 480	Level: 6	Refer to appendix 1

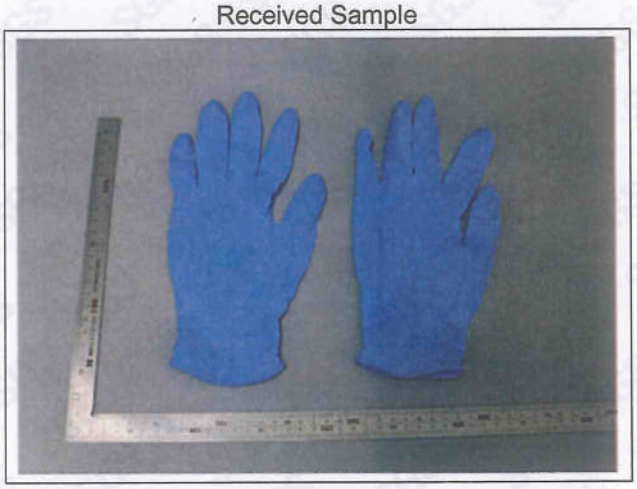
Appendix 1:

Permaton performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Remark: The test was carried out by external laboratory assessed as competent (Jiangsu Guojian Testing Technology Co., Ltd, CMA No. 161019130764).

Sample Photo:

Received Sample



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End of Report

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SGS

Test Report

Client name	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Client address	:	ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO. 99, JINJIHU AVENUE, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, CHINA
Sample Description	:	MEDICAL NITRILE INSPECTION GLOVES
Lot No.	:	20200610001
Lot Size	:	100000
Sample Quantity	:	400PCS
Manufacturer	:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Manufacturer Date	:	JUN.10,2020
Appearance	:	BLUE SMOOTH FINGER HEMP HALOGEN FREE GLOVES
Storage Condition	:	ROOM TEMPERATURE

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date	:	JUN.23,2020
Test Performing Date	:	JUN.23,2020 TO JUL.09,2020

****

Test Requested	Result
1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
2. BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3)	Pass
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4)	Pass

Note: -Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.
The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

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Technical Services (Qingdao)
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QDHL2006005935MD

Jessica Gao
Approved Signatory

Test Conducted:

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

Number of test sample	:	200 Pieces
Sample size	:	M
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:0. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

2. **BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties**

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves: b)
Size	:	Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	241	96
2	246	97
3	247	96
4	245	97
5	240	94
6	244	96
7	244	96
8	245	97
9	243	97
10	241	95
11	243	95
12	242	95
13	241	96
Standard requirement	≥240	95±10
Median value	243	96

Result 2: Strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	6.0	1	5.6
2	6.8	2	6.7
3	6.7	3	6.6
4	7.7	4	7.4
5	6.7	5	5.7
6	6.8	6	6.1
7	6.5	7	6.3
8	6.3	8	6.0
9	7.1	9	6.6
10	6.2	10	6.1
11	5.8	11	6.6
12	6.6	12	6.5
13	6.4	13	5.7
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	6.6	Median value	6.3

3. **BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation**

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Size	:	M

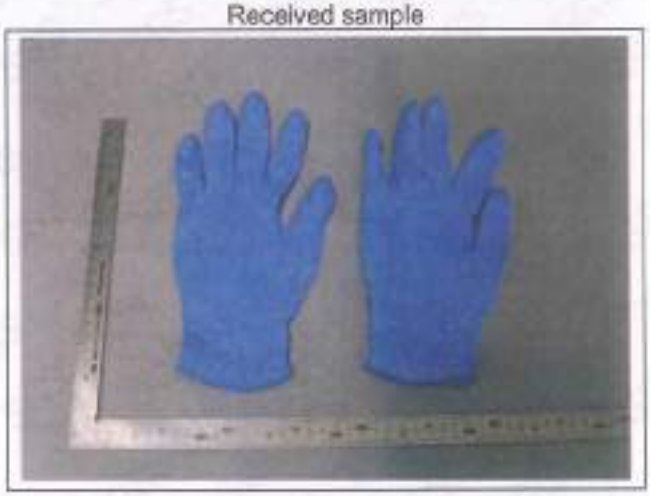
Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.10mg. (Requirement: ≤2mg per powder-free glove)

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received sample



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*** End of Report ***

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TESTING
CNAS L0604

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QDHL2105504184MD

Test Report

Report No.: QDHL2105504184MD

Sample Description:	DISPOSABLE POWDER FREE NITRILE GLOVES
Applicant:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Test Type:	SUBMITTED BY CLIENT

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Report No.: QDHL2105504184MD

Test Report

Sample information	Sample Description	DISPOSABLE POWDER FREE NITRILE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	500PCS/ 231PCS	Size	L
	Lot No.	SYF-ST01	Lot Quantity	NOT PROVIDED
	Manufacture Date	2021-04-01	Expiration Date	5 YEARS
	Material	NITRILE		
	Manufacturer	NOT PROVIDED		
	Others	EXAMINATION GLOVES; POWDER-FREE GLOVES		
Client information	Applicant	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD		
	Applicant address	ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99,JINJIHU AVENUE, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, CHINA		

Report No.: QDHL2105504184MD

Test information	Sample Receiving Date	MAY.21,2021	Test Period Date	MAY.21,2021 TO JUN.08,2021
	Sample No.	QDHL2105504184MD	Test environment	Meet requirement
	Test items	Watertightness, Dimension (Length, Width), Tensile strength (Force at break, Force at break after challenge testing), Powder-free gloves		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1 EN 455-2:2015 Medical Gloves for Single Use–Part 2: Requirements and Testing for Physical Properties clause 4.2, 4.3, 5.2, 5.3 EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: JUN.08,2021			
Remark	/			

Approver: Jessica Co Auditor: Crystal Sun Compiler: Lillian Diao

Date: JUN.08,2021 Date: JUN.08,2021 Date: JUN.08,2021

Report No.: QDHL2105504184MD

Sample Photo


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Report No.: QDHL2105504184MD

Test Results

Test Items		Unit	Test Method	Requirement		Test Result	Assessment
Watertightness		/	EN 455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8		Found: 0	Pass
Dimension	Length	mm	EN 455-2: 2015 Clause 4.2	Median value: L: ≥240	Sample quantity: 13pcs	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: L: 110±10			Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: b): ≥6.0	Sample quantity: 13pcs	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: b): ≥6.0			Pass
Removable surface powder (Powder-free gloves)		mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006 Method B	Sample quantity: 5pcs Average: ≤2		0.1	Pass

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Report No.: QDHL2105504184MD

Appendix 1: Dimension

Size	L	
No.	Length (mm)	Width (mm)
1	240	106
2	240	106
3	241	106
4	240	106
5	240	106
6	240	106
7	240	106
8	243	106
9	240	107
10	240	106
11	240	107
12	240	106
13	240	106
Standard requirement	≥240	110±10
Median value	240	106

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Report No.: QDHL2105504184MD

Appendix 2: Tensile Strength

Size: L			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	6.1	1	6.5
2	7.6	2	7.7
3	7.9	3	7.1
4	7.9	4	6.5
5	7.5	5	6.5
6	8.1	6	6.6
7	8.1	7	7.3
8	6.6	8	6.8
9	8.3	9	6.9
10	7.4	10	6.4
11	6.6	11	6.8
12	6.8	12	6.6
13	6.2	13	6.1
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	7.5	Median value	6.6

Remark:The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.

2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

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INGEER CERTIFICATION ASSESSMENT SERVICES

医疗器械质量管理体系
认 证 证 书

认证编号：117 21 Q0M 0036 R0S

兹证明 **苏州十一方生物科技有限公司**

统一社会信用代码：**91320594MA1MXDLB8J**

注册地址：**中国（江苏）自由贸易试验区苏州片区苏州工业园区金鸡湖大道99号苏州纳米城西北区12栋302室**

经营地址：**江苏省苏州市工业园区金鸡湖大道99号苏州纳米城西北区12栋302室**

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Certification No. 117 21 Q0M 0036 R0S

This is to certify that **Suzhou SHIYIFANG Biotechnology Co., Ltd**

Unified social credit code 91320594MA1MXDLB8J

Registered Address Room 302, Building 12, Northwest Area, Suzhou Nano City, No. 99, Jinjihu Avenue, Suzhou Industrial Park, Suzhou Area, China (Jiangsu) Pilot Free Trade Zone

Business Address Room 302, Building 12, Northwest Area, Suzhou Nano City, No. 99, Jinjihu Avenue, Suzhou Industrial Park, Jiangsu Province, China

has been assessed and registered as meeting the requirements of

ISO13485:2016

Scope of approval Production Outsourcing and Sales of Medical Examination Gloves (Class I Medical Devices)

First Certification: 04 Feb. 2021

Expiry Date: 03 Feb. 2024

Signed by: _____

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