JIXIANG® MEDICAL

Fujian Jixiang
Medical Group

福建集翔医疗科技有限公司

Fujian Jixiang Medical Technology Co., Ltd

2020-11-18

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Jixiang
Medical Group

地理位置 Location

长汀县（汀州府城）

简称“汀”，隶属福建省，是中央苏区汀州市所在地

[1] 、红旗跃过汀江的地方

[2] 、 位于福建省西部，武夷山脉南麓，南邻广东、西接江西；自古为闽、粤、赣三省边陲要冲，被誉为“福建省西大门”。

[3] 、长汀历称汀州，汉代置县，自唐开元二十四年置汀州始，成为福建五大州、七闽地、八闽府之一。自盛唐以来的一千多年里，长汀一直是州、郡、路、府治所在地，是“客家文化（闽西）生态保护实验区”的科教文化中心 。

[4] 、长汀亦称汀州府，是客家人聚居的第一座府治城市，被誉为“世界客家首府”。长汀还是国务院批复的第三批国家历史文化名城（1994年）、中国烹饪协会首个颁布的中国客家菜之乡（2004年），享有“福建美食名城”、“红军的故乡”、“红色小上海”的称号 。

[5] 、长汀融人文景观与自然景观于一体，被“中国的十大国际友人”路易·艾黎誉为“中国最美丽的山城”。

[6] 、 2012年获“中国十大最具人文底蕴古城古镇”称号。长汀成为全国第一批“绿水青山就是金山银山”实践创新基地、首批国家生态文明建设示范市（县），成为福建省唯一同时获得这两个称号（授牌）的县（市）。2018年3月成为第一批通过全国水生态文明建设试点验收城市 。
[7] 、 2019年3月，被列为第一批革命文物保护利用片区分县名单。
[8] 、 2019年度福建省县域经济发展“十佳”县（市）。
[9] 、 2020年5月，被列入国家级县城新型城镇化建设示范名单。

2019年，全县地区生产总值达（以四经普为基数核算）289.75亿元，按可比价格计算，增长7.4%

Changting County (Tingzhou Fucheng)

Referred to as "Ting", belongs to Fujian Province, is the seat of The Central Suzhou District Tingzhou City

[1] Where the red flag jumps over the Ting River.
[2] It is located in the west of Fujian Province, at the southern foot of Wuyi Mountain, adjacent to Guangdong in the south and Jiangxi in the west. Since ancient times, it has been the border crossing of Fujian, Guangdong and Jiangxi province, and is known as the "western gate of Fujian province".
[3] In the Changting calendar, Tingzhou was established as a county in the Han Dynasty. Since it was established in The 24th year of the Kaiyuan of the Tang Dynasty, It has become one of the five provinces of Fujian, the seven provinces of Fujian and the eight Provinces of Fujian. For more than one thousand years since the tang Dynasty, Changting has been the seat of prefecture, county, road and government, and the scientific, educational and cultural center of "Hakka Culture (Western Fujian) Ecological Protection Experimental Area".
[4] Changting, also known as Tingzhou Capital, is the first prefecture city inhabited by Hakka people and is honored as the "Hakka capital of the world". Changting is also the third batch of national historical and cultural cities approved by the State Council (1994), the first Chinese Hakka cuisine issued by the Chinese Culinary Association (2004), and enjoys the title of "Fujian cuisine city", "hometown of the Red Army", "Red Little Shanghai".
[5] Changting integrates cultural landscape with natural landscape, and is praised as "The most beautiful mountain city in China" by "China's Top ten International Friends" Louis Reille.
[6] In 2012, it won the title of "Top Ten Ancient Towns with The Most Cultural Deposits in China". Changting became the first batch of practice and innovation bases of "clear water and green mountains are gold and silver mountains" and the first batch of demonstration cities (counties) of national ecological civilization construction, and became the only county (city) in Fujian Province to win both of these titles (awarding). In March 2018, it became the first batch of cities to pass the national pilot inspection of water ecological civilization construction.
[7] In March 2019, it was listed as one of the first counties for the protection and utilization of revolutionary cultural relics.
[8]. "Top ten" counties (cities) in County economic Development of Fujian Province in 2019.[9] In May 2020, it was included in the demonstration list of new-type urbanization construction of state-level counties.In 2019, the county's gross domestic product (GDP) reached 28.975 billion yuan (calculated from the base of the four jingpu), an increase of 7.4% at comparable prices

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Jixiang
Medical Group

选择长汀 Choose the Changding

医疗无界限 –
中国首位开国医疗学专业中将 傅连璋

1894年出生于长汀县河田镇伯公岭村,1925年被推举为长汀县福音医院院长。红军起义初期无偿收治红军伤员,红军长征期间数次为军中发生的各种传染病提出解决办法和医治方案,并主张为红军官兵接种疫苗,避免病情的扩散。此后更担任毛主席保健医生,多次有效维护了毛主席身体健康,免于传染病与疾病的侵扰。新中国成立后历任中央卫生部副部长,中华医学会会长等重要职务,为中国传染病防治体系奠定了不可抹灭功绩。

2020年新冠疫情肆虐全球，长汀县政府迅速筹建『防疫物资生产基地』，提供给防疫物资生产企业多项优惠政策和扶持，本着『人溺己溺』的慈悲胸怀积极招揽各地优质生产企业，为提供给全球各地迫切需要的防疫物资做出充分努力，这无疑是将长汀**『医疗无界限』**的精神升华的体现。
福建集翔医疗集团于是选择落地长汀，为这场人类文明史上有记载以来最大的传染病疫情投入防疫物的生产。

Medical treatment knows No boundaries –

China's first pioneer of medical science, Lt. Gen. - Lian Zhang FU

He was born in Bogongling Village, Hetian Town, Changting County in 1894, and was elected President of Changting County Evangelion Hospital in 1925. In the early days of the Red Army uprising, the wounded were admitted and treated free of charge. During the Long March, the Red Army provided solutions and medical treatment for various infectious diseases in the army on several occasions, and advocated vaccinating the Red Army officers and soldiers to prevent the spread of diseases. Since then, he also served as chairman MAO's health care doctor, and repeatedly effectively maintained Chairman MAO's health, free from infectious diseases and diseases. Since the founding of the People's Republic of China, he has served successively as vice Minister of the Central Health Ministry and President of the Chinese Medical Association, which have made ineffable contributions to China's infectious disease prevention and control system.Around the world in 2020 outbreak of the new champions league and changting county government's rapid preparation "epidemic prevention materials production base", provide epidemic prevention material production enterprises a number of preferential policies and support, in line with the "people drowned oneself drowned" compassion around the mind actively attract high-quality production enterprises, to provide the world desperately needs full efforts of epidemic prevention materials, this is undoubtedly the changting "health without boundaries," the spirit of sublimation.Fujian Jixiang Medical Group then chose to land in Changting, for the history of human civilization since the largest recorded epidemic of infectious diseases into the production of epidemic prevention products.

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Company Profile

企业概况 Enterprise brief introduction

Fujian Jixiang Medical Technology Co., Ltd

福建集翔医疗科技有限公司

Fujian Jixiang Medical Technology Co., Ltd. (hereinafter referred to as the Company) is a large-scale medical devices enterprise with the funding of China National Pharmaceutical Group Co., Ltd. (Sinopharm) and Xiamen Hansen Group Co., Ltd., which is introduced by the People`s Government of Changting County, Fujian Province

福建集翔医疗科技有限公司(以下简称公司)是一家由福建省长汀县人民政府招商引资，由国药集团和厦门瀚森集团投资建设的大型医疗器械类企业，

Founded in August, 2020, the Company is located in No. 29 Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, boasting a total area of 170,000 square meters and a plant of 50,000 square meters. At present, its main products have been medical and household gloves made of PVC, latex, nitrile, etc.. Relying on the registered capital of 100 million RMB and the total investment of 1,050 million RMB, the Company plans to build 39 large-scale automatic production lines with a length of 180 meters. By then, with the joint efforts of more than 100 technicians and 800 employees, the Company is able to reach an annual output of 7 billion gloves, paying a tax of at least 100 million RMB each year. The scale of production and sales ranks the first in Fujian Province.

公司成立于2020年8月，坐落于福建长汀县策武镇汀州大道29号，占地面积为17万平方米，厂房面积50000平方米，目前主要产品为PVC、乳胶、丁腈等医用手套民用手套。公司注册资本为1亿元人民币，第一阶段总投资为10.5亿元人民币，公司共计划投建200条丁腈及乳胶生产，300条混丁,合成及PVC生产线。第一批次将建成39条180米长的大型全自动生产线，60条全新混丁合成及PVC产线，届时将年产450亿只手套，各项专业技术人员200余人，员工2800余人，年纳税额将超过2亿元人民币以上。在同行业中产、销规模全省第一。

Fujian Jixiang Medical Technology Co., Ltd

福建集翔医疗科技有限公司

In the spirit of unity, innovation, excellence, cooperation and leadership, the Company has been adhering to the humanized management, upholding the business philosophy of science and technology constitute a primary productive force, and regarding R&D and innovation as the cornerstone to improve、the competitiveness. So far, all production lines are independently developed by the Company, which reflects its scientific and technological strength. Sticking to the marketing strategy of dwelling on domestic markets and exploiting overseas markets, the Company has set up a long-term strategic goal of promoting international cooperation. Its products now find a good sale in Southeast Asia, Africa, Europe and other regions.

团结、创新、卓越、共赢、领航是公司的宗旨和精神，公司始终秉持人性化的管理理念，以科技是第一生产力作为企业发展的主调，永远把研发和创新当着企业提高竞争力的基石。目前所有生产线，皆为公司自主研发，拥有较高的技术含量。公司以“站稳国内，开拓国际市场”积极推进国际化作为企业长远的战略发展目标。并逐步实现产品远销东南亚、非欧等地区。

The Company attaches great importance to brand awareness. While improving the ability and quality of management unceasingly, Jixiang people always uphold their creed of quality first, brand first. With unremitting efforts to occupy a leading position in China and even the world, the Company strives to build the reputation of Jixiang products both at home and abroad within two years.

公司重视品牌意识，在不断提升公司管理水平、管理质量的基础上，坚持“质量第一，品牌至上”是集翔人永恒的信条，公司力争在二年内打响“集翔”牌产品在国内外的知名度，为跻身全国乃至世界前列不懈努力。

福建集翔获得长汀政府大力扶持！

Fujian Jixiang Medical Technology Co., Ltd

福建集翔医疗科技有限公司

福建集翔获得长汀政府大力扶持！

Fujian Jixiang Medical Technology Co., Ltd

福建集翔医疗科技有限公司

Technical support 技术支撑

Our company's equipment is configured by the domestic professional equipment research and development team, the daily capacity can reach 1.09 million, is the domestic production line with the highest daily capacity.

我们公司设备由国内专业设备研发团队配置，日产能可达109万只，是国内目前日产能最高的生产线。

The company's glove commissioning team is made up of engiAneer Zou, who has been engaged in glove commissioning for more than 20 years. Engineer Zou has been invited by dozens of glove factories at home and abroad to commissioning equipment

公司手套调试团队由从业超20年的邹工程师为核心组成，邹工程师曾受到国内外数十家手套厂邀请到厂调试设备

建线进度预估表（战略合作伙伴合作新建线数量未列入）

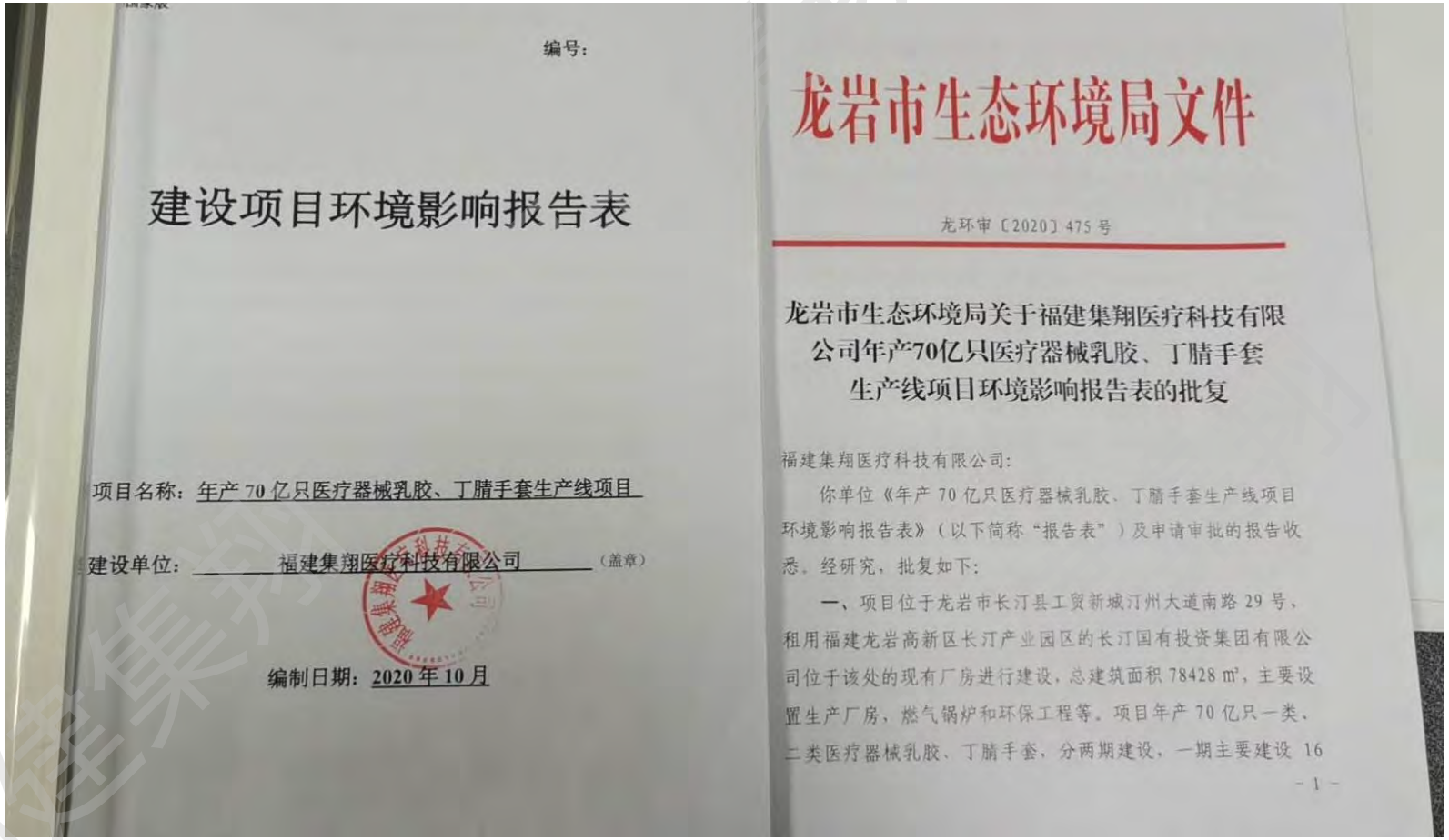
福建集翔丁腈手套生产线生产计划表（三十九条生产线）						
设备编号	框架完成日期	设备安装完成	调试	生产	手套产量（每天万只）	手套产量（每月万只）
第一条线	9月20日	10月20日	10月30日	12月10日	109	3052
第二条线	9月20日	10月30日	11月10日	12月15日	218	6104
第三条线	9月30日	12月20日	12月30日	1月8日	327	9156
第四条线	9月30日	12月20日	12月30日	1月8日	436	12208
第五条线	10月10日	12月20日	12月30日	1月8日	545	15260
第六条线	10月10日	12月20日	12月30日	1月8日	654	18312
第七条线	10月10日	1月10日	1月20日	1月30日	763	21364
第八条线	10月10日	1月10日	1月20日	1月30日	872	24416
第九条线	11月20日	1月10日	1月20日	1月30日	981	27468
第十条线	11月20日	1月10日	1月20日	1月30日	1090	30520
第十一条线	11月20日	1月10日	1月20日	1月30日	1199	33572
第十二条线	11月20日	1月20日	1月30日	2月10日	1308	36624
第十三条线	11月20日	1月20日	1月30日	2月10日	1417	39676
第十四条线	11月20日	1月20日	1月30日	2月10日	1526	42728
第十五条线	11月20日	1月20日	1月30日	2月10日	1635	45780
第十六条线	11月20日	1月20日	1月30日	2月10日	1744	48832
第十七条线	12月30日	1月20日	1月30日	2月10日	1853	51884
第十八条线	12月30日	1月20日	1月30日	2月10日	1962	54936

建线进度预估表（战略合作伙伴合作新建线数量未列入）

福建集翔丁腈手套生产线生产计划表（三十九条生产线）						
设备编号	框架完成日期	设备安装完成	调试	生产	手套产量（每天万只）	手套产量（每月万只）
第十九条线	12月30日	1月30日	2月20日	3月1日	2071	57988
第二十条线	12月30日	1月30日	2月20日	3月1日	2180	61040
第二十一条线	12月30日	1月30日	2月20日	3月1日	2289	64092
第二十二条线	12月30日	1月30日	2月20日	3月1日	2398	67144
第二十三条线	12月30日	1月30日	2月20日	3月1日	2507	70196
第二十四条线	12月30日	1月30日	2月20日	3月1日	2616	73248
第二十五条线	12月30日	1月30日	2月20日	3月1日	2725	76300
第二十六条线	12月30日	1月30日	2月20日	3月1日	2834	79352
第二十七条线	12月30日	1月30日	2月20日	3月1日	2943	82404
第二十八条线	12月30日	2月27日	3月25日	3月30日	3052	85456
第二十九条线	1月20日	2月27日	3月25日	3月30日	3161	88508
第三十条线	1月20日	2月27日	3月25日	3月30日	3270	91560
第三十一条线	1月20日	2月27日	3月25日	3月30日	3379	94612
第三十二条线	1月20日	2月27日	3月25日	3月30日	3488	97664
第三十三条线	1月20日	2月27日	3月25日	3月30日	3597	100716
第三十四条线	1月20日	2月27日	3月25日	3月30日	3706	103768
第三十五条线	1月20日	2月27日	3月25日	3月30日	3815	106820
第三十六条线	1月20日	2月27日	3月25日	3月30日	3924	109872
第三十七条线	1月20日	2月27日	3月25日	3月30日	4033	112924
第三十八条线	1月20日	2月27日	3月25日	3月30日	4142	115976
第三十九条线	1月20日	2月27日	3月25日	3月30日	4251	119028

Certificate of approval of EIA

环评审评通过证明



编号：

建设项目环境影响报告表

项目名称：年产 70 亿只医疗器械乳胶、丁腈手套生产线项目

建设单位：福建集翔医疗科技有限公司（盖章）

编制日期：2020 年 10 月

龙岩市生态环境局文件

龙环审〔2020〕475 号

龙岩市生态环境局关于福建集翔医疗科技有限公司年产70亿只医疗器械乳胶、丁腈手套生产线项目环境影响报告表的批复

福建集翔医疗科技有限公司：

你单位《年产 70 亿只医疗器械乳胶、丁腈手套生产线项目环境影响报告表》（以下简称“报告表”）及申请审批的报告收悉。经研究，批复如下：

一、项目位于龙岩市长汀县工贸新城汀州大道南路 29 号，租用福建龙岩高新区长汀产业园区的长汀国有投资集团有限公司位于该处的现有厂房进行建设，总建筑面积 78428 ㎡，主要设置生产厂房，燃气锅炉和环保工程等。项目年产 70 亿只一类、二类医疗器械乳胶、丁腈手套，分两期建设，一期主要建设 16

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WID ERANGE

OF PREMIUM QUILITY

优质产品 High quality products

Examination gloves (Powder-free)

丁腈检查手套　无 粉

QUILTYFEATURES

Biologically compatible
Softness and shape provides excellent comfort
Beaded cuff enhances donning and prevent rollback
High tensile strength and elongation

质量特征：

生物相容性
柔软性和准确形状提供了极好的舒适性
珠状袖口增强了穿戴感，防止后卷高拉伸强度和伸长率

Examination gloves (Powder-free)

丁腈检查手套　无 粉

采用100%合成丁腈橡胶胶乳(丙烯腈丁二烯)制造与相同厚度的天然橡胶胶乳相比，可抵御多种化学品。

强度更高，抗穿刺性更好。

生物相容性.

柔软性和准确形状提供了极好的舒适性

珠状袖口增强了穿戴感，防止后卷

高拉伸强度和伸长率.

双手灵巧，手指可伸直。

无污垢痕迹、油污、嵌入的异物颗粒、凝结物等。完全不含滑石粉。

全纹理可抓握，在各种条件下都能获得出色的性能。

Examination gloves (Powder-free)

丁腈检查手套　无 粉

PRODUCT SPECIFICATIONS

Material –Synthetic Nitrile Rubber Latex
(Acrylonitrile
Butadiene) Length –240 mm +/- 5mm
Weight –4.0to 6.0g +/- 0.3g per piece Cuff Style
–
Beaded
Surface –Palm Textured AQL –1- 2.5

产品规格

材料–合成丁腈橡胶胶乳(丙烯腈丁二烯)长度 –
240mm+/-5mm
重量–3.5至6.0克+/-0.3克/件袖口风格–珠状表面–棕
榈纹理AQL–1-2.5

Examination gloves polymer coated(Powder-free)

聚合物涂层乳胶检查手套　无 粉

QUILTYFEATURES

Biologically compatible
Softness and shape provides excellent comfort Beaded cuff enhances donning and prevent rollback High tensile strength and elongation
Ambidextrous and straight fingers

质量特征：

生物相容性
柔软性和准确形状提供了极好的舒适性
珠状袖口增强了穿戴感，防止后卷高拉伸强度和伸长率

Examination gloves polymer coated(Powder-free)

聚合物涂层乳胶检查手套　无 粉

PRODUCT SPECIFICATIONS

Material – Synthetic Nitrile Rubber Latex (Acrylonitrile Butadiene) Length – 240 mm +/- 5mm
Weight – 3.5 to 6.0g +/- 0.3g per piece Cuff Style – Beaded
Surface – Palm Textured AQL – 1 - 2.5

产品规格

材料–合成丁腈橡胶胶乳(丙烯腈丁二烯)长度 – 240mm+/-5mm
重量–3.5至6.0克+/-0.3克/件袖口风格–珠状表面–棕榈纹理AQL–1-2.5

Examination gloves (Powder-free)

乳胶检查手套　无 粉

Manufactured with high quality and innovative manufacturing technology that makes the glove soft and provides excellent comfort. Beaded cuff enhances donning and prevents rollback.
High tensile strength and elongation. Ambidextrous and straight fingers.
Free from dirt marks, oil stains, embedded foreign particles, coagulum etc.
Extra washing and leaching reduces the possibility of allergic reactions to minimum level.
Polymer Coated for easy donning.
Fully textured grip for great performance in all conditions.

采用高质量创新制造技术制造，使手套柔软舒适。珠状袖口加强了穿戴和防止回卷。
高拉伸强度和伸长率.
双手灵巧，手指可伸直。
无污垢痕迹、油污、嵌入的异物颗粒、凝结物等。额外的洗涤和沥滤将过敏反应的可能性降至最低水平。聚合物涂层，便于穿戴。
全纹理可抓握，在各种条件下都能获得出色的性能。

Examination gloves (Powder-free)

乳胶检查手套　无 粉

QUALITY STANDARDS

Conforms to EN 455 standards.
Manufactured under QRS (GMP) and ISO 9001:2015 ,ISO 14001:2015 Quality Management System CE certified and TUV Standard
SGS Test report and FDA registration Hypoallergenic reducing potential allergic reactions. etc.

质量标准

符合EN455标准。
根据QRS (GMP)和ISO 9001:2015、ISO 14001:2015质量管理体系CE认证和TUV标准制造根据QRS (GMP)和ISO 9001:2015、ISO 14001:SGS报告
和美国食品和药物管理局注册。
低过敏性，减少潜在的过敏反应。等等。

S, M, L, XL

PVC gloves

聚氯乙烯手套

质量标准

·符合EN455及EN374相关标准
·符合ASTMD5250相关标准（美国市场产品）
·符合EN455及EN374相关标准
·符合ASTMD5250相关标准（美国市场产品）
·拥有美国食药监局FDA510 (K)注册

产品特性

·不含DOP及DEHP
·无乳胶蛋白，相关过敏人士的良好选择
·可用于食品处理，但油脂类食品除外
·有粉及无粉产品可选
·为多种物质提供良好防护
·超软轻柔
·具有良好手感，佩戴舒适
AQL水平1.5 I 2.5 I 4,0可选

福建集翔聚氯乙烯手套有粉及无粉系列以100%全新改良配方的材料，带来比以往产品更为轻软的感受，同时确保对多种物质和微生物良好的防护。 这是良好感受与物理特性的平衡，同时是对乳胶手套中蛋白过敏人士的良好替代方案。

Synthetic gloves

混丁. 合成手套

质量标准

·符合EN455及EN374相关标准
·符合ASTMD5250相关标准（美国市场产品）

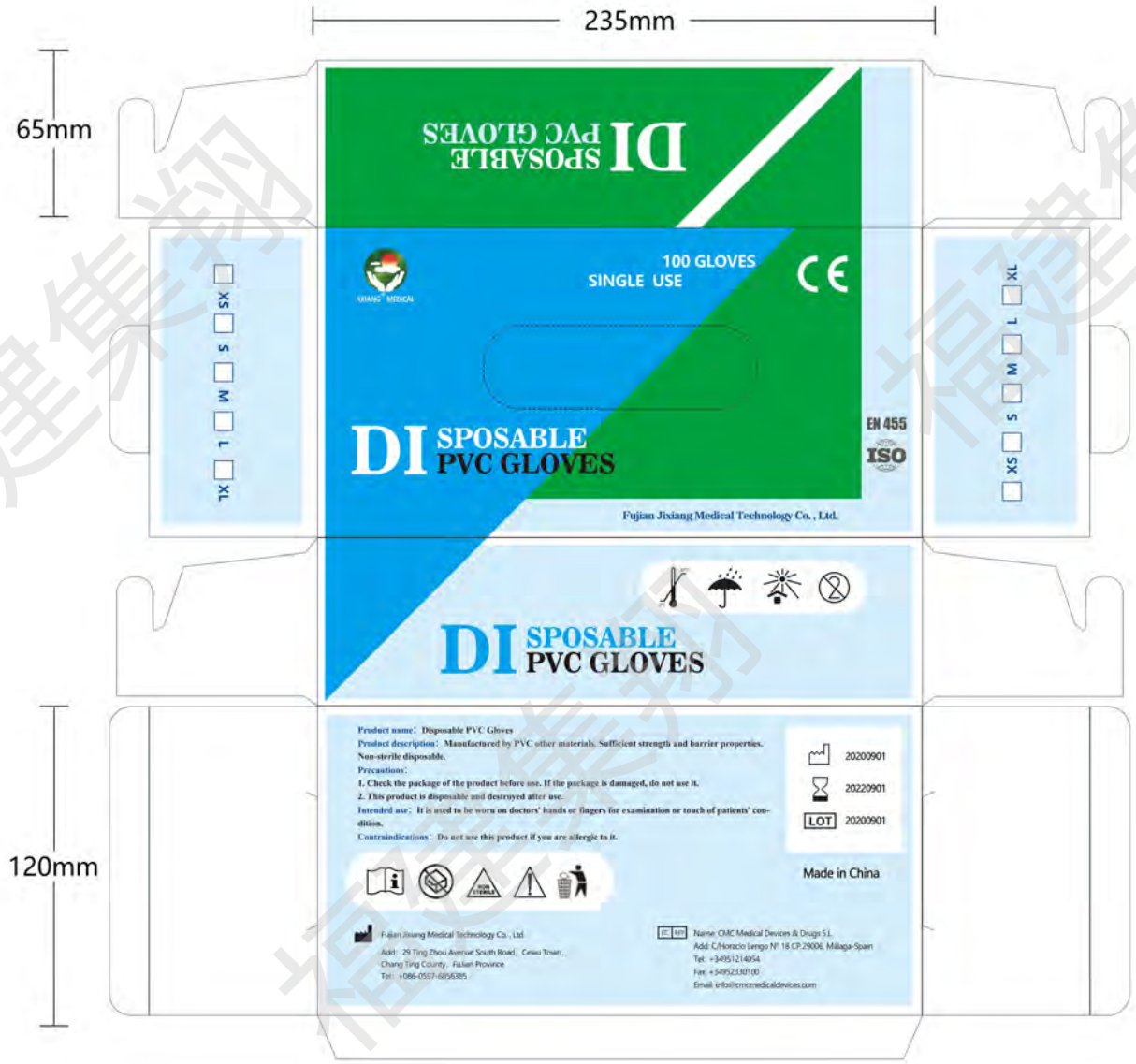
产品特性

·全新一代检查手套产品
·不含DOP及DEHP
·无天然乳胶蛋白，极低过敏风险
·接近天然乳胶的舒适手感
·全面的防护性与超强韧性
·增强的敏锐手感
·蓝色、 白色、 紫色粉色等多种流行色
·最具性价比的手部保护方案

革命性的第四代检查手套，全新的聚氯乙烯基复合材料确保了接近橡胶的弹性手感与强韧 " 骨感 ' 。新材料带来全面的防护与敏锐手感，更是乳胶蛋白过敏人士的上佳之选。

OUR
EXCLUSIVERANGE

OUR
EXCLUSIVERANGE



OUR
EXCLUSIVERANGE

QUALITY ASSURANCE

质量保证

Product meets all started and implied needs. Manufactured under hygiene and environment control. Superior barrier protection. Scientifically tested gloves. Standardized and Customized Packing. Well equipped microbiology lab. State-of-the-art manufacturing inspection, and packing facilities.

产品满足所有已开始和隐含的需求。 在卫生和环境控制下制造。

卓越的屏障保护。

经过科学测试的手套。

标准化和定制包装。

设备完善的微生物实验室。

最先进的制造检验和包装设施。

Specifications

现有产品规格

产品品名	型号	净重（KGS）	尺寸	单位	毛重重（千克）	包装方式	装箱尺寸	照片
丁腈手套	S	4.0	9英寸	只	5.3	100只/盒 10盒/箱	31.5x26.5x25.5cm 1300箱/20尺距 3300箱/40尺距	
	M	4.5	9英寸	只	5.85			
	L	5.0	9英寸	只	6.35			
	XL	5.5	9英寸	只	6.85			

产品品名	型号	净重（KGS）	尺寸）	单位	毛重（千克）	包装方式	装箱尺寸	照片
PVC 手套	S	4.0	9英寸	只	4.85	100只/盒 10盒/箱	31.5x26.5x25.5cm 1300箱/20尺距 3300箱/40尺距	
	M	4.5	9英寸	只	5.35			
	L	5.0	9英寸	只	5.85			
	XL	5.5	9英寸	只	6.35			

产品品名	型号	净重（KGS）	尺寸	只	毛重（千克）	包装方式	装箱尺寸	照片
一次性混合丁腈手套	S	3.8	9英寸	只	4.65	100只/盒 10盒/箱	31.5x26.5x25.5cm 1300箱/20尺距 3300箱/40尺距	
	M	4.3	9英寸	只	5.15			
	L	4.8	9英寸	只	6.65			
	XL	5.3	9英寸	只	6.15			

产品品名	型号	净重（KGS）	尺寸	只	毛重（千克）	包装方式	装箱尺寸	照片
乳胶手套	S	5.0	9英寸	只	5.85	100只/盒 10盒/箱	31.5x26.5x25.5cm 1300箱/20尺距 3300箱/40尺距	
	M	5.5	9英寸	只	6.35			
	L	6.0	9英寸	只	6.85			
	XL	6.5	9英寸	只	7.35			

examining report butyronitrile

国标检测报告医用级丁腈 Nitrile GB 10213-2006


深圳市计量质量检测研究院

检 验 报 告

TEST REPORT

报告编号：WT209631374

产品名称：一次性丁腈手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀洲大道南路 29 号

生产单位：福建集翔医疗科技有限公司

生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号

检测日期：2020 年 10 月 11 日-2020 年 10 月 21 日

检测类别：委托检测

深圳市计量质量检测研究院　批准人：邓海英

签发日期：2020.10.21　签名：邓海英


报告编号：WT208020576

检 测 报 告


报告编号：WT208020576

检验报告


报告编号：WT208020576

产品照片


报告编号：WT208020576

说 明

1、报告无骑缝章和检验检测专用章无效。

2、报告无签发人签名无效，报告经涂改、增删无效。

3、未经本检测机构书面同意，不得部分复印本检测报告，未经同意不得作为商业广告使用。

4、带*标准项目不在本实验室 CMA、CMA 认可范围内，本报告只对送检样品检测结果负责。

5、委托本单位对本检测报告有异议，请在收到报告之日或规定领取报告之日起，7 个工作日内提出申诉，逾期不予受理。

6、除客户特别申明并支付样品管理费，所有超过标准规定时效期的样品均不再做留样。

深圳市计量质量检测研究院

examining report butyronitrile

国标检测报告医用级丁腈　Nitrile GB 10213-2006


深圳市计量质量检测研究院

检 验 报 告

TEST REPORT

报告编号：WT208020576

产品名称：丁腈检查手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀洲大道南路 29 号

生产单位：福建集翔医疗科技有限公司

生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号

检测日期：2020 年 08 月 19 日-2020 年 09 月 15 日

检测类别：委托检测

深圳市计量质量检测研究院　批准人：邓海英

签发日期：2020.09.16　签名：邓海英


报告编号：WT208020576

检 测 报 告


报告编号：WT208020576

检验报告


报告编号：WT208020576

产品照片


报告编号：WT208020576

说 明

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2、报告无签发人签名无效，报告经涂改、增删无效。

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5、委托本单位对本检测报告有异议，请在收到报告之日或指定领取报告之日起，于 个工作日内提出申诉，逾期不予受理。

6、请客户特别申明并支付样品管理费，所有超出标准规定时效期的样品后不再做维样。

福 建 集 翔

Fujian Jixiang

examining report butyronitrile

SGS检测报告医用级丁腈　　EN 455

SGS

Test Report　No.: XMHL2010010152CW　Date: Nov 02, 2020　Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN PROVINCE

Sample Description : NITRILE GLOVES

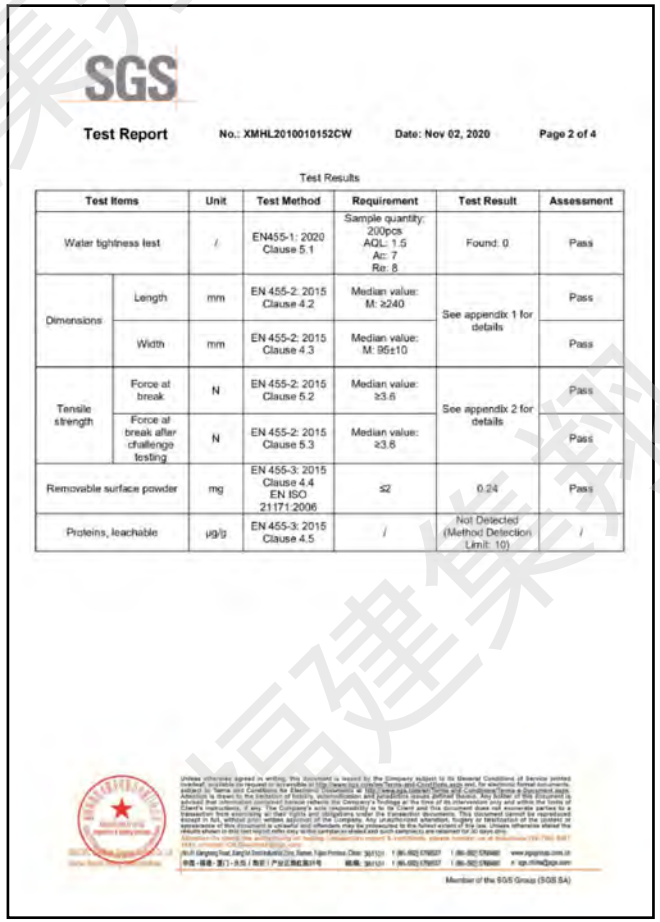
As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

SGS Ref No. : QDHL2010010736MD
Sample Receiving Date : Oct 10, 2020
Test Performing Date : Oct 10, 2020 to Nov 02, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory



SGS

Test Report　No.: XMHL2010010152CW　Date: Nov 02, 2020　Page 2 of 4

Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass
Dimensions	Length	mm	EN 455-2: 2015 Clause 4.2	Median value: M: ≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: M: 95±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: ≥3.6	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: ≥3.6		Pass
Removable surface powder		mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171:2006	≤2	0.24	Pass
Proteins, leachable		μg/g	EN 455-3: 2015 Clause 4.5	/	Not Detected (Method Detection Limit: 10)	/

examining report PVC

SGS检测报告医用级PVC GB 24786-2009

检 验 报 告

TEST REPORT

报告编号：WT208020575

产品名称：pvc 一次性手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀州大道南路 29 号

生产单位：福建集翔医疗科技有限公司

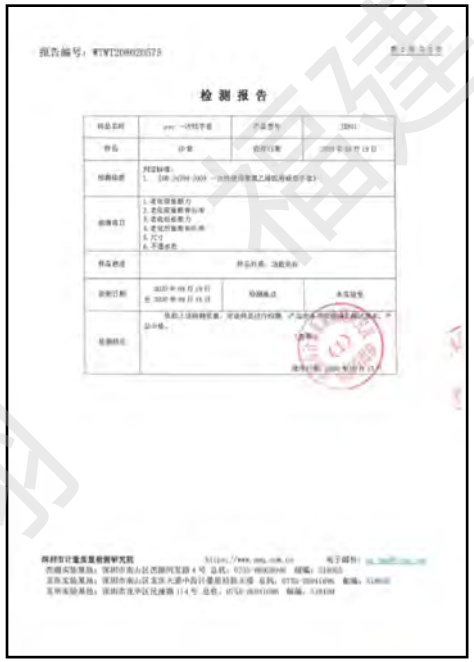
生产单位地址：福建省长汀县策武镇汀州大道南路 29 号

检测日期：2020 年 08 月 19 日-2020 年 09 月 15 日

检测类别：委托检测

深圳市计量质量检测研究院 批准人：邓海英

签发日期：2020. 09. 15 签名：邓海英



报告编号：WTWT208020575

检 测 报 告

报告编号：WTWT208020575

检验报告

报告编号：WTWT208020575

产品照片

报告编号：WTWT208020575

说 明

1、报告无骑缝章和检验检测专用章无效。

2、报告无签发人签名无效，报告经涂改，增删无效。

3、未经本检测机构书面同意，不得部分复印本检测报告，未经同意不得作为商业广告使用。

4、带*标准项目不在本实验室 CMA、CNA 认可范围内，本报告只对送检样品检测结果负责。

5、委托本单位对本检测报告有异议，请在收到报告之日或指定领取报告之日起，7 个工作日内提出申诉，逾期不予受理。

6、除客户特别申明并支付样品管理费，所有超过标准规定时效期的样品均不再做留样。

examining report PVC

SGS检测报告医用级PVC　EN 455

SGS

Test Report　No.: XMHL2010010076CW　Date: Oct 28, 2020　Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD,CEWU TOWN,CHANGTING COUNTY,FUJIAN PROVINCE

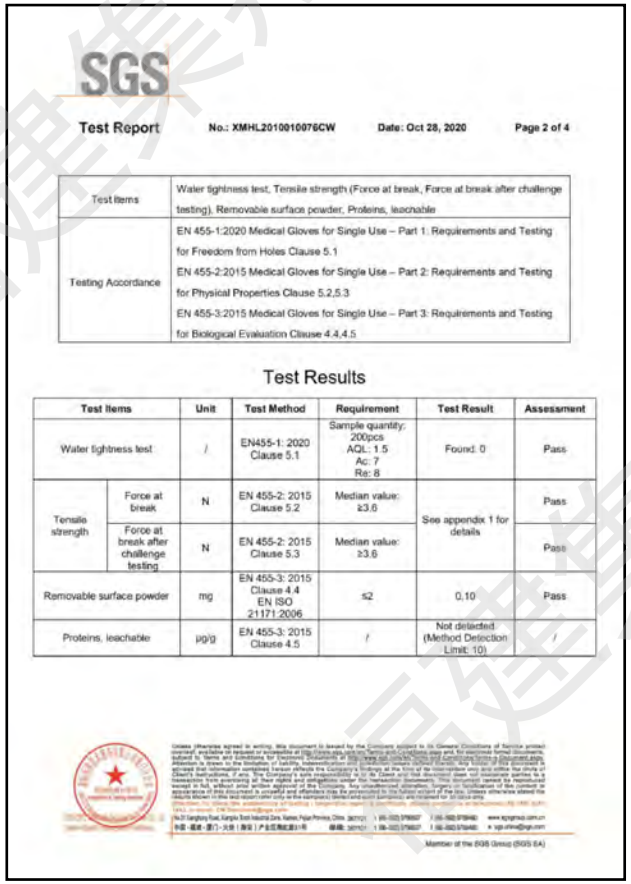
Sample Description : DISPOSABLE PVC GLOVES

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.

SGS Ref No. : QDHL2010010644MD
Sample Receiving Date : Oct 10, 2020
Test Performing Date : Oct 10, 2020 to Oct 28, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory



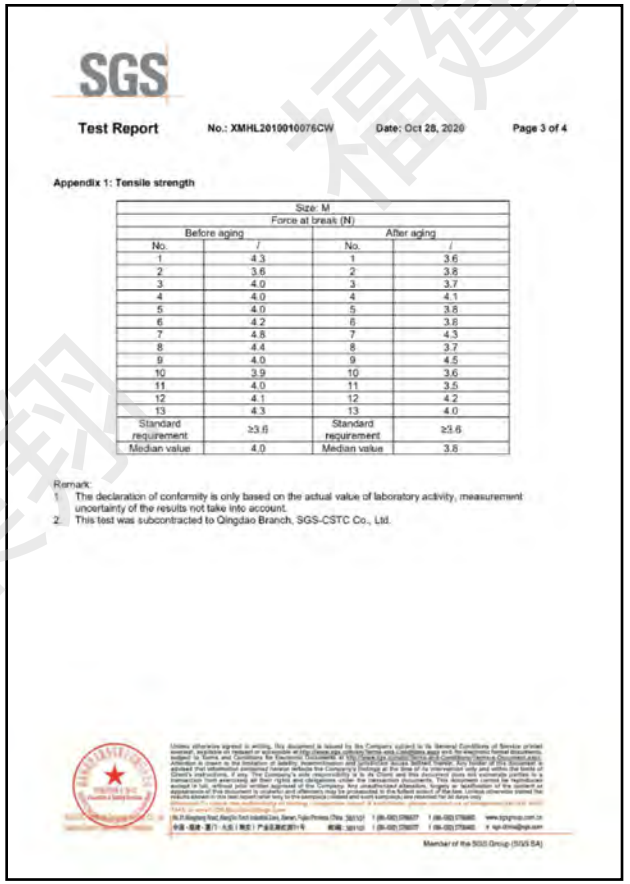
SGS

Test Report　No.: XMHL2010010076CW　Date: Oct 28, 2020　Page 2 of 4

Test Items	Water tightness test, Tensile strength (Force at break, Force at break after challenge testing), Removable surface powder, Proteins, leachable
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 5.2,5.3 EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation Clause 4.4,4.5

Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 0	Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: ≥3.6	See appendix 1 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: ≥3.6		Pass
Removable surface powder		mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171:2006	≤2	0.10	Pass
Proteins, leachable		μg/g	EN 455-3: 2015 Clause 4.5	/	Not detected (Method Detection Limit: 10)	/



SGS

Test Report　No.: XMHL2010010076CW　Date: Oct 28, 2020　Page 3 of 4

Appendix 1: Tensile strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	4.3	1	3.6
2	3.6	2	3.8
3	4.0	3	3.7
4	4.0	4	4.1
5	4.0	5	3.8
6	4.2	6	3.8
7	4.8	7	4.5
8	4.4	8	3.7
9	4.0	9	4.5
10	3.9	10	3.6
11	4.0	11	3.5
12	4.1	12	4.2
13	4.3	13	4.0
Standard requirement	≥3.6	Standard requirement	≥3.6
Median value	4.0	Median value	3.8

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

examining report PVC

SGS检测报告医用级PVC　EN 455

SGS

Test Report　No.: XMHL2010010076CW　Date: Oct 28, 2020　Page 4 of 4

Sample Photo

End of Report

SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN RPOVINCE

Sample Description : LATEX GLOVES

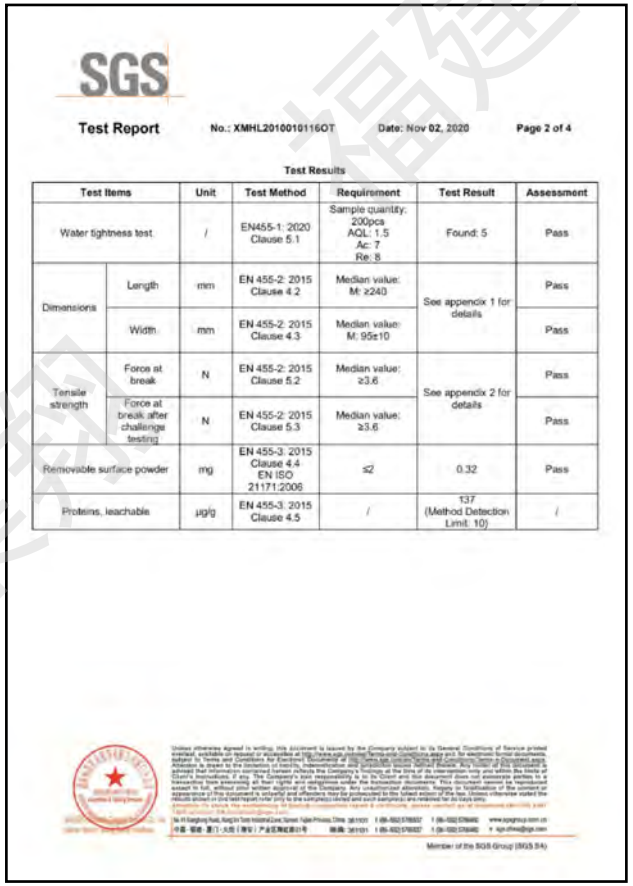
As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant, SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

SGS Ref No. : QDHL2010010737MD
Sample Receiving Date : Oct 12, 2020
Test Performing Date : Oct 12, 2020 to Nov 02, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory



SGS

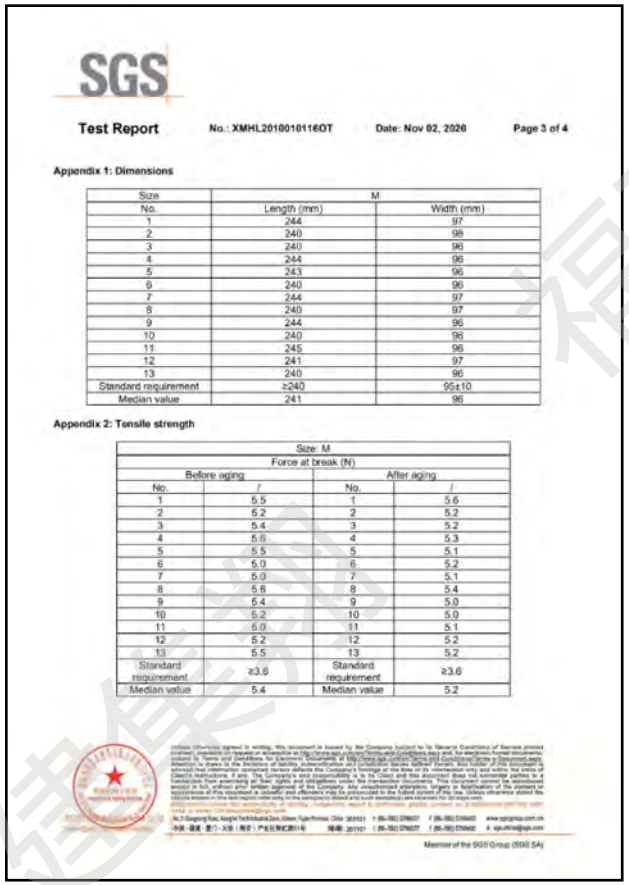
Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 2 of 4

Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 5	Pass
Dimensions	Length	mm	EN 455-2: 2015 Clause 4.2	Median value: M: ≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: M: 95±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: ≥3.6	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: ≥3.6		Pass
Removable surface powder		mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171:2006	≤2	0.32	Pass
Proteins, leachable		μg/g	EN 455-3: 2015 Clause 4.5	/	137 (Method Detection Limit: 10)	/

examining report PVC

SGS检测报告医用级PVC　EN 455



SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 3 of 4

Appendix 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	244	97
2	240	98
3	240	96
4	244	96
5	243	96
6	240	96
7	244	97
8	240	97
9	244	96
10	240	96
11	245	96
12	241	97
13	240	96
Standard requirement	≥240	95±10
Median value	241	96

Appendix 2: Tensile strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	5.5	1	5.6
2	5.2	2	5.2
3	5.4	3	5.2
4	5.6	4	5.3
5	5.5	5	5.1
6	5.0	6	5.2
7	5.0	7	5.1
8	5.6	8	5.4
9	5.4	9	5.0
10	5.2	10	5.0
11	5.0	11	5.1
12	5.2	12	5.2
13	5.5	13	5.2
Standard requirement	≥3.6	Standard requirement	≥3.6
Median value	5.4	Median value	5.2

SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 4 of 4

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

Sample photo(s):

The testing report/certificate only refers to the sample(s) tested.
End of Report

examining report PVC

国标检测报告食品级PVC　　　GB 4806.7-2016


深圳市计量质量检测研究院

检 验 报 告

TEST REPORT

报告编号：WT208020762

产品名称：pvc 一次性手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀洲大道南路 29 号

生产单位：福建集翔医疗科技有限公司

生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号

检测日期：2020 年 08 月 日-2020 年 09 月 15 日

检测类别：委托检测

深圳市计量质量检测研究院　　批准人：邓海昊

签发日期：2020.09.15　　签名：


检 测 报 告


检 验 报 告


产品图片


说 明

examining report Latex

国标检测报告医用级乳胶　　GB 10213-2006

深圳市计量质量检测研究院
Shenzhen Academy of Metrology & Quality Inspection

检 验 报 告
TEST REPORT

报告编号：WT208020642
产品名称：乳胶检查手套
委托单位：福建集翔医疗科技有限公司
单位地址：福建省长汀县策武镇汀洲大道南路 29 号
生产单位：福建集翔医疗科技有限公司
生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号
检测日期：2020 年 08 月 19 日-2020 年 09 月 15 日
检测类别：委托检测

深圳市计量质量检测研究院　批准人：邓海英
签发日期：2020. 09. 15　签名：邓海英

检 测 报 告

检验报告

产品照片

说 明

examining report Latex

SGS检测报告医用级乳胶　EN 455

SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD, CEWU TOWN, CHANGTING COUNTY, FUJIAN RPOVINCE

Sample Description : LATEX GLOVES

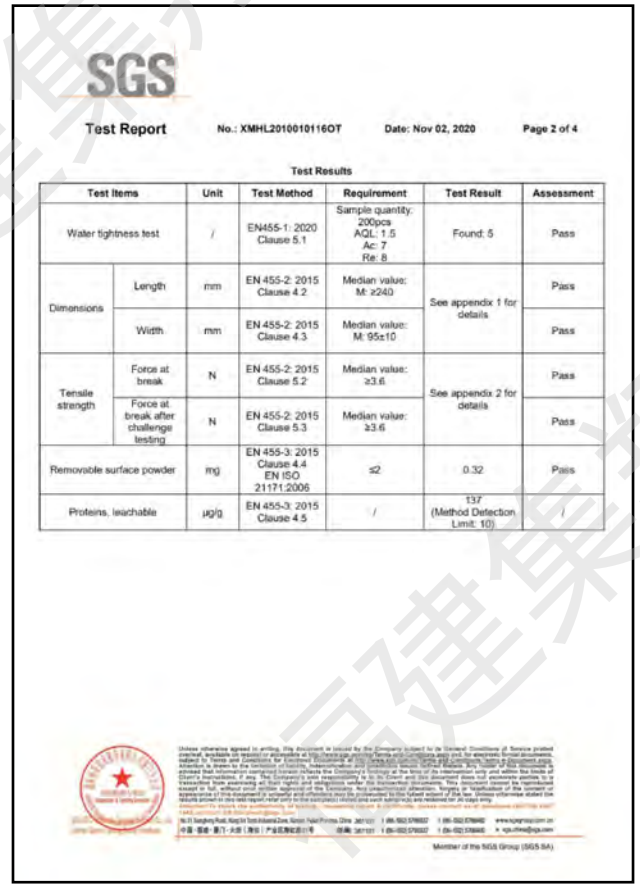
As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant, SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

SGS Ref No. : QDHL2010010737MD
Sample Receiving Date : Oct 12, 2020
Test Performing Date : Oct 12, 2020 to Nov 02, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory



SGS

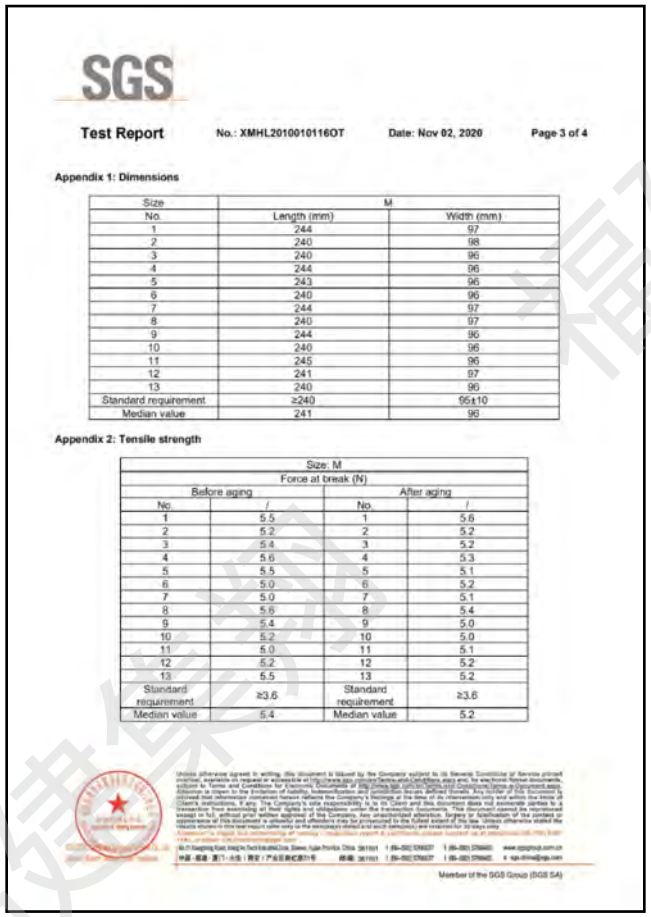
Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 2 of 4

Test Results

Test Items		Unit	Test Method	Requirement	Test Result	Assessment
Water tightness test		/	EN455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8	Found: 5	Pass
Dimensions	Length	mm	EN 455-2: 2015 Clause 4.2	Median value: M: ≥240	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: M: 95±10		Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: ≥3.6	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: ≥3.6		Pass
Removable surface powder		mg	EN 455-3: 2015 Clause 4.4 EN ISO 21171:2006	≤2	0.32	Pass
Proteins, leachable		μg/g	EN 455-3: 2015 Clause 4.5	/	137 (Method Detection Limit: 10)	/

examining report Latex

SGS检测报告医用級乳胶　EN 455



SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 3 of 4

Appendix 1: Dimensions

Size	M	
No.	Length (mm)	Width (mm)
1	244	97
2	240	98
3	240	96
4	244	96
5	243	96
6	240	96
7	244	97
8	240	97
9	244	96
10	240	96
11	245	96
12	241	97
13	240	96
Standard requirement	≥240	95±10
Median value	241	96

Appendix 2: Tensile strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	5.5	1	5.6
2	5.2	2	5.2
3	5.4	3	5.2
4	5.6	4	5.3
5	5.5	5	5.1
6	5.0	6	5.2
7	5.0	7	5.1
8	5.6	8	5.4
9	5.4	9	5.0
10	5.2	10	5.0
11	5.0	11	5.1
12	5.2	12	5.2
13	5.5	13	5.2
Standard requirement	≥3.6	Standard requirement	≥3.6
Median value	5.4	Median value	5.2

SGS

Test Report　No.: XMHL2010010116OT　Date: Nov 02, 2020　Page 4 of 4

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

Sample photo(s):

The testing report/certificate only refers to the sample(s) tested.
End of Report

examining report Synthetic

国标检测报告医用级混丁 Synthetic GB 10213-2006

深圳市计量质量检测研究院

检 验 报 告

TEST REPORT

报告编号：WT2091063726

产品名称：一次性混合丁腈检查手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀洲大道南路 29 号

生产单位：福建集翔医疗科技有限公司

生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号

检测日期：2020 年 10 月 30 日-2020 年 11 月 06 日

检测类别：委托检测

深圳市计量质量检测研究院 批准人：

签发日期：2020.09.15 签名：

报告编号：WT2091063726 第 4 页，共 4 页

检 测 报 告

报告编号：WT2091063726 第 4 页，共 4 页

检验报告

报告编号：WT2091063726 第 4 页，共 4 页

产品照片

报告编号：WT2091063726 第 4 页，共 4 页

说 明

1、报告无骑缝章和检验检测专用章无效。

2、报告无签发人签名无效，报告经涂改、增删无效。

3、未经本检测机构书面同意，不得部分复印本检测报告，未经同意不得作为商业广告使用。

4、非标准或项目不在本实验室 CMA、CMA 认可范围内，本报告只对送检样品检测结果负责。

5、委托本单位对本检测报告有异议，请在收到报告之日或指定领取报告之日起，7 个工作日内提出申诉，逾期不予受理。

6、除客户特别申明并支付样品管理费，所有超过标准规定时效期的样品均不再额留样。

examining report Synthetic

国标检测报告医用级蓝色合成防护   Synthetic GB 10213-2006

深圳市计量质量检测研究院

检 验 报 告

TEST REPORT

报告编号：WT2091063354

产品名称：蓝色合成防护手套

委托单位：福建集翔医疗科技有限公司

单位地址：福建省长汀县策武镇汀洲大道南路 29 号

生产单位：福建集翔医疗科技有限公司

生产单位地址：福建省长汀县策武镇汀洲大道南路 29 号

检测日期：2020 年 10 月 29 日-2020 年 11 月 06 日

检测类别：委托检测

深圳市计量质量检测研究院　　批准人：何月行

签发日期：2020.11.06　　签名：何月行

检 测 报 告

报告编号：WT2091063354

检验报告

测试项目	测试方法	限量	测试结果	单项判定

报告编号：WT2091063354

产品照片

说 明

examining report Nitrile

美标检测报告丁腈手套 ASTM D6319

SGS

Test Report No.: XMHL2011011076OT Date: Dec 12, 2020 Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD,CEWU TOWN,CHANGTING COUNTY,FUJIAN PROVINCE

Sample Description : NITRILE GLOVES

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.

SGS Ref No. : QDHL2011012519MD
Sample Receiving Date : Nov 23, 2020
Test Performing Date : Nov 23, 2020 to Dec 12, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Test information	Test items	Freedom from holes, Physical dimensions (Length, Width, Thickness), Powder residue for powder free gloves
	Testing Accordance	ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application Clause 6.1.2, 6.1.3, 6.1.5.
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: DEC.11,2020	
Remark	/	

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory

SGS

Test Report No.: XMHL2011011076OT Date: Dec 12, 2020 Page 2 of 4

Test Items		Unit	Test Method	Requirement		Test Result	Assessment
Performance Requirements							
Freedom from Holes		/	ASTM D6319-19 Clause 7.3	Sample quantity: 200pcs AQL: 2.5 Ac: 10 Re: 11		Found: 0	Pass
Physical dimensions	Length	mm	ASTM D6319-19 Clause 7.4	L: ≥230	Sample quantity: 13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 1 for details	Pass
	Width	mm		L: 110±10 Median Value ≥0.05			Pass
	Thickness-finger	mm					Pass
	Thickness-palm	mm		Median Value ≥0.05			Pass
Powder Residue For Powder Free Gloves		mg	ASTM D6319-19 Clause 7.6	≤2.0		0.14	Pass

SGS

Test Report No.: XMHL2011011076OT Date: Dec 12, 2020 Page 3 of 4

Appendix 1: Physical dimensions

Sample No.	Size: L			
	Length/mm	Width /mm	Median value /mm	
			Thickness-finger	Thickness-palm
1	235	113	0.088	0.071
2	234	112	0.093	0.071
3	236	113	0.081	0.063
4	234	112	0.093	0.064
5	236	112	0.081	0.065
6	233	112	0.074	0.061
7	237	113	0.096	0.069
8	237	112	0.065	0.068
9	234	113	0.083	0.063
10	235	113	0.084	0.064
11	235	112	0.088	0.059
12	237	112	0.079	0.062
13	239	113	0.092	0.060
Standard requirement	≥230	110±10	≥0.05	≥0.05
Found	0	0	0	0

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

SGS

Test Report No.: XMHL2011011076OT Date: Dec 12, 2020 Page 4 of 4

Sample Photo

End of Report

examining report Latex

美标检测报告乳胶手套 ASTM D3578

SGS

Test Report No.: XMHL2011011073OT Date: Dec 12, 2020 Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD,CEWU TOWN,CHANGTING COUNTY,FUJIAN PROVINCE

Sample Description : LATEX GLOVES

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.

****

SGS Ref No. : QDHL2011012818MD
Sample Receiving Date : Nov 23, 2020
Test Performing Date : Nov 23, 2020 to Dec 12, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Test Information	Test Items	Freedom from Holes, Physical dimensions (Length, Width, Thickness), Powder residue for powder free gloves
	Testing Accordance	ASTM D 3578-19 Standard Specification for Rubber Examination Gloves Clause 7.1.2, 7.1.3, 7.1.5
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: DEC 11,2020	
Remark	/	

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory

SGS

Test Report No.: XMHL2011011073OT Date: Dec 12, 2020 Page 2 of 4

Test Items		Unit	Test Method	Requirement		Test Result	Assessment
Freedom from Holes		/	ASTM D 3578-19 Clause 8.3	Sample quantity: 200pcs AQL: 2.5 Ac: 10 Re: 11		Found: 1	Pass
Physical dimensions	Length	mm	ASTM D 3578-19 Clause 8.4	L: ≥230	Sample quantity: 13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 1 for details	Pass
	Width	mm	ASTM D 3578-19 Clause 8.4	L: 111±10			Pass
	Thickness-finger	mm	ASTM D 3578-19 Clause 8.4	Median Value: ≤0.08			Pass
	Thickness-palm	mm		Median Value: ≥0.08			Pass
Powder Residue For Powder Free Gloves		mg	ASTM D 3578-19 Clause 8.6	≤2.0		0.84	Pass

SGS

Test Report No.: XMHL2011011073OT Date: Dec 12, 2020 Page 3 of 4

Appendix 1: Physical Dimensions

Sample No.	Size: L			
	Length (mm)	Width (mm)	Median value (mm)	
			Thickness-finger	Thickness-palm
1	246	106	0.107	0.090
2	243	106	0.110	0.086
3	247	106	0.114	0.097
4	251	106	0.105	0.094
5	245	107	0.110	0.086
6	245	106	0.102	0.086
7	243	106	0.107	0.090
8	246	107	0.114	0.092
9	242	106	0.103	0.090
10	246	106	0.102	0.083
11	248	106	0.109	0.089
12	242	106	0.112	0.090
13	243	106	0.103	0.090
Standard requirement	≥230	111±10	≤0.08	≥0.08
Found	0	0	0	0

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

SGS

Test Report No.: XMHL2011011073OT Date: Dec 12, 2020 Page 4 of 4

Sample Photo

End of Report

examining report PVC

美标检测报告PVC手套 ASTM D5250

Test Report No.: XMHL2011011072OT Date: Dec 12, 2020 Page 1 of 4

FUJIAN JIXIANG MEDICAL TECHNOLOGY CO.,LTD
29 TINGZHOU AVENUE SOUTH ROAD,CEWU TOWN,CHANGTING COUNTY,FUJIAN PROVINCE

Sample Description : DISPOSABLE PVC GLOVES

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.

****

SGS Ref No. : QDHL2011012815MD
Sample Receiving Date : Nov 23, 2020
Test Performing Date : Nov 23, 2020 to Dec 12, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Test information	Test items	Physical property characteristics (Tensile strength & Ultimate elongation before aging, Tensile strength & Ultimate elongation after aging)
	Testing Accordance	ASTM D 5250-19 Standard Specification for Poly (Vinyl Chloride) Gloves for Medical Application Clause 6.1.4
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: DEC 11,2020	
Remark	/	

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch

Beck Hong
Authorized Signatory

Test Report No.: XMHL2011011072OT Date: Dec 12, 2020 Page 2 of 4

Test Items			Unit	Test Method	Requirement		Test Result	Assessment
Performance Requirements								
Physical property characteristics	Before Aging	Tensile strength	MPa	ASTM D 5250-19 Clause 7.5	≥11	Sample quantity: 13pcs AQL: 4.0 Ac: 1 Re: 2	See appendix 1 for details	Pass
		Ultimate Elongation	%		≥300			
	After Aging	Tensile strength	MPa		≥11			
		Ultimate Elongation	%		≥300			

Test Report No.: XMHL2011011072OT Date: Dec 12, 2020 Page 3 of 4

Appendix 1: Physical property characteristics

Size: L					
Before Aging			After Aging		
Sample No.	Tensile strength (MPa)	Ultimate Elongation (%)	Sample No.	Tensile strength (MPa)	Ultimate Elongation (%)
1	20.7	358	1	16.4	316
2	19.3	359	2	18.4	316
3	16.4	306	3	15.5	312
4	20.6	370	4	16.1	333
5	17.6	327	5	17.0	326
6	17.5	326	6	16.2	316
7	18.5	351	7	16.7	300
8	18.9	331	8	17.3	330
9	21.3	383	9	19.7	363
10	19.4	334	10	16.3	317
11	19.0	377	11	20.0	360
12	16.5	341	12	16.4	305
13	19.7	359	13	18.1	340
Standard requirement	≥11	≥300	Standard requirement	≥11	≥300
Found	0	0	Found	0	0

Remark:
1. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
2. This test was subcontracted to Qingdao Branch, SGS-CSTC Co., Ltd.

Test Report No.: XMHL2011011072OT Date: Dec 12, 2020 Page 4 of 4

Sample Photo

End of Report

福 建 集 翔
Fujian Jixiang

examining report Nitrile

EN ISO21420 ISO374 丁腈

SATRA TECHNOLOGY

Customer details: Fujian Jixiang Medical Technology Co., Ltd. No. 29 Tingzhou Avenue, Ceeu Town, Changting County, Fujian Province, China

SATRA reference: CHT0305551 /2048
Your reference: MDJ01
Date of report: 23 December 2020
Samples received: 27 November 2020
Date(s) work carried out: 1-18 December 2020

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak test on Disposable Powder free Nitrile gloves referenced as MDJ01, colour: Blue, Purple, size: 6, 7, 8

Conditions of Issue:

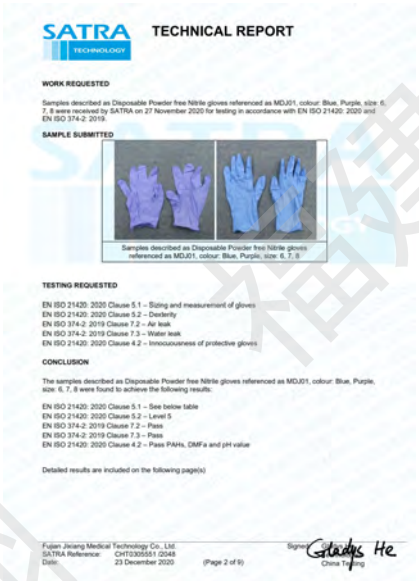
This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

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



SATRA TECHNOLOGY — TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, colour: Blue, Purple, size: 6, 7, 8 were received by SATRA on 27 November 2020 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 MDJ01, colour: Blue, Purple, size: 6, 7, 8

TESTING REQUESTED

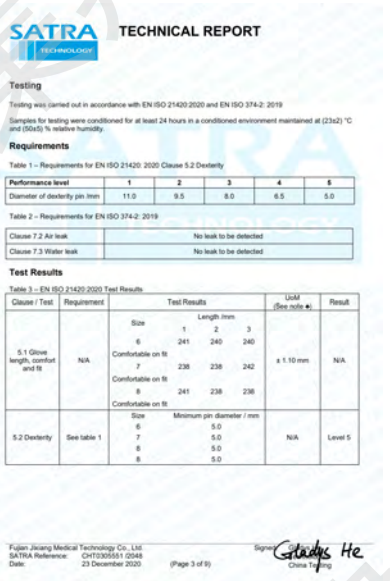
EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 374-2: 2019 Clause 7.2 – Air leak
EN ISO 374-2: 2019 Clause 7.3 – Water leak
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, colour: Blue, Purple, size: 6, 7, 8 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, DMFa and pH value

Detailed results are included on the following page(s)



SATRA TECHNOLOGY — TECHNICAL REPORT

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

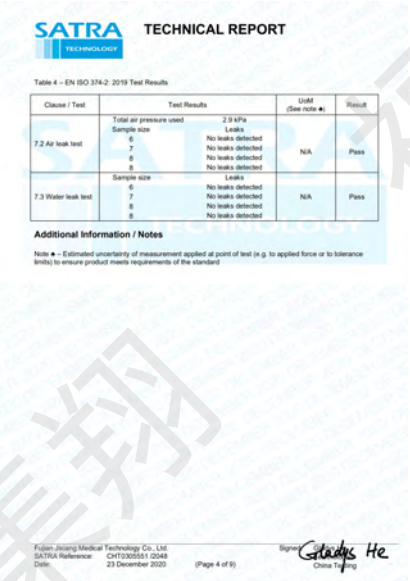
Table 2 – Requirements for EN 374-2: 2019

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	± 1.10 mm	N/A
		6	241	240	240		
		Comfortable on fit					
		7	238	238	242		
		Comfortable on fit					
		8	241	238	238		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				
		8	5.0				



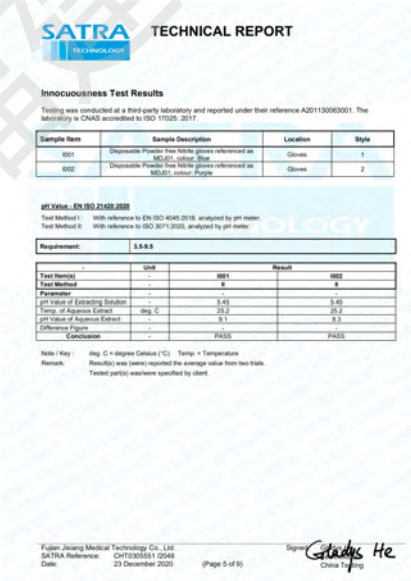
SATRA TECHNOLOGY — TECHNICAL REPORT

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		
	8	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		
	8	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



SATRA TECHNOLOGY — TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A201130063001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder free Nitrile gloves referenced as MDJ01, colour: Blue	Gloves	1
I002	Disposable Powder free Nitrile gloves referenced as MDJ01, colour: Purple	Gloves	2

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 / I002
Test Method	-	II / II
Parameter	-	-
pH Value of Extracting Solution	-	5.45 / 5.45
Temp. of Aqueous Extract	deg. C	25.2 / 25.2
pH Value of Aqueous Extract	-	9.1 / 8.3
Difference Figure	-	- / -
Conclusion	-	PASS / PASS

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

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EN ISO21420 ISO374 丁腈

SATRA TECHNOLOGY

TECHNICAL REPORT

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+ I002	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 hydrocarbons is summarized in table of Appendix.
Tested part(s) was/were specified by client.
Composite testing(s) was/were specified by client.

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

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SATRA TECHNOLOGY

TECHNICAL REPORT

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+ I002	
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
Remark: Tested part(s) was/were specified by client.
Composite testing(s) was/were specified by client.

*** End of Report ***

Fujian Jixiang Medical Technology Co., Ltd.
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Date: 23 December 2020 (Page 7 of 9)
Signed: Gladys He, China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

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

Fujian Jixiang Medical Technology Co., Ltd.
SATRA Reference: CHT0305551/2048
Date: 23 December 2020 (Page 8 of 9)
Signed: Gladys He, China Testing

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TECHNICAL REPORT

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

Fujian Jixiang Medical Technology Co., Ltd.
SATRA Reference: CHT0305551/2048
Date: 23 December 2020 (Page 9 of 9)
Signed: Gladys He, China Testing

examining report Nitrile

EN ISO21420 ISO374 -3 丁腈

SATRA TECHNOLOGY

SATRA Technology Centre Ltd
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Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305890/2049/LH A
Your reference: CHT0305551
Date of report: 13th January 2021
Samples received: 30th November 2020
Date(s) work carried out: 16th December 2020 to 11th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Cewu Town,
Changling County,
Fujian Province,
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple

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.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 8)

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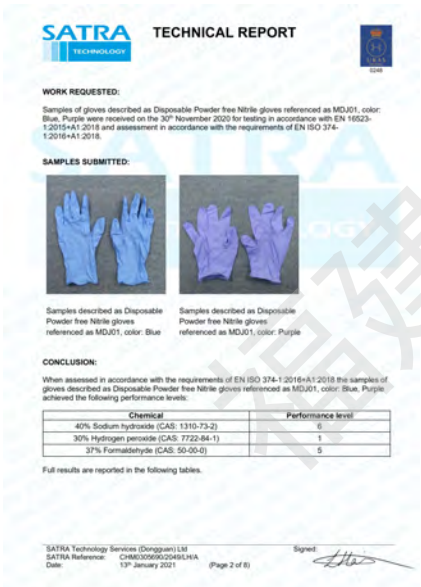

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple were received on the 30th November 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:

Samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue

Samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Purple

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	1
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.

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SATRA Reference: CHM0305890/2049/LH/A
Date: 13th January 2021
(Page 2 of 8)
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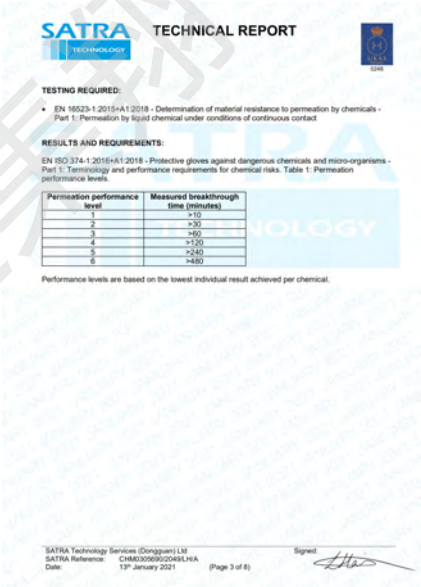

SATRA TECHNOLOGY

TECHNICAL REPORT

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels

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

Performance levels are based on the lowest individual result achieved per chemical.

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Date: 13th January 2021
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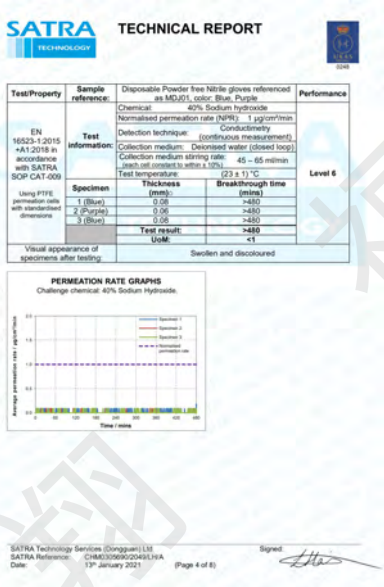

SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple	Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium hydroxide	Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min	
		Detection technique: Conductimetry (continuous measurement)	
		Collection medium: Deionised water (closed loop)	
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)	
		Test temperature: (23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins):
	1 (Blue)	0.08	>480
	2 (Purple)	0.06	>480
	3 (Blue)	0.08	>480
		Test result:	>480
		UoM:	<1
Visual appearance of specimens after testing:	Swollen and discoloured		

PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide.

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SATRA Reference: CHM0305890/2049/LH/A
Date: 13th January 2021
(Page 4 of 8)
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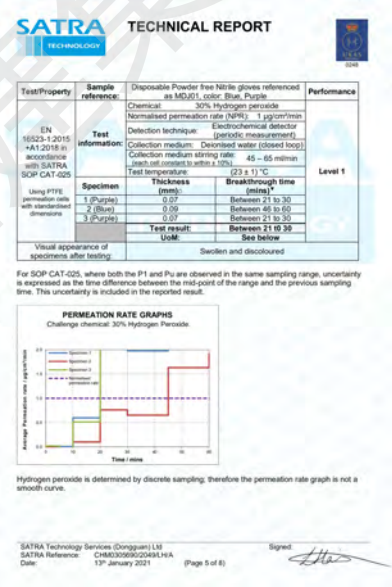

SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple	Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide	Level 1
		Normalised permeation rate (NPR): 1 µg/cm²/min	
		Detection technique: Electrochemical detector (periodic measurement)	
		Collection medium: Deionised water (closed loop)	
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)	
		Test temperature: (23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins):
	1 (Purple)	0.07	Between 21 to 30
	2 (Blue)	0.09	Between 46 to 60
	3 (Purple)	0.07	Between 21 to 30
		Test result:	Between 21 t0 30
		UoM:	See below
Visual appearance of specimens after testing:	Swollen and discoloured		

For SOP CAT-025, where both the P1 and Pu are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

PERMEATION RATE GRAPHS
Challenge chemical: 30% Hydrogen Peroxide.

Hydrogen peroxide is determined by discrete sampling, therefore the permeation rate graph is not a smooth curve.

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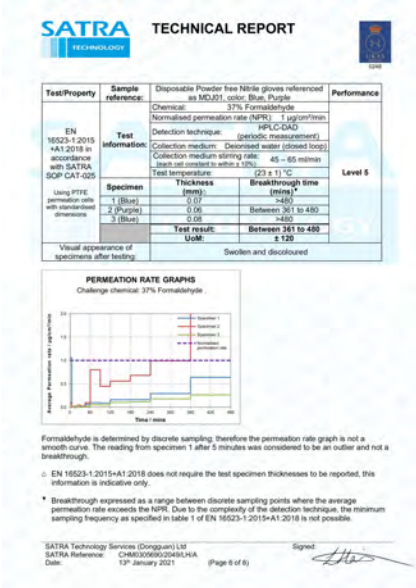

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Test/Property	Sample reference:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical:	37% Formaldehyde	Level 5
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	HPLC-DAD (periodic measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%):	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1 (Blue)	0.07	>480	
	2 (Purple)	0.06	Between 361 to 480	
	3 (Blue)	0.08	>480	
		Test result:	Between 361 to 480	
		UoM:	± 120	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde .

Formaldehyde is determined by discrete sampling, therefore the permeation rate graph is not a smooth curve. The reading from specimen 1 after 5 minutes was considered to be an outlier and not a breakthrough.

Δ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

* Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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

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SATRA Reference: CHM0305690/2049/LHIA
Date: 13th January 2021 (Page 8 of 8)
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Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305690/2049/LH/B
Your reference: CHT0305551
Date of report: 13th January 2021
Samples received: 30th November 2020
Date(s) work carried out: 10th to 12th January 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Cewu Town,
Changting County,
Fujian Province,
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple.

Conditions of issue:

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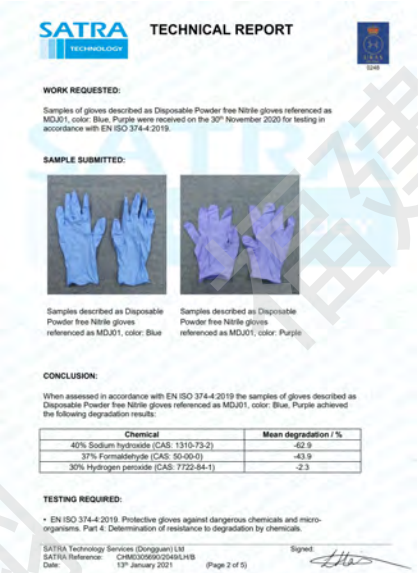
The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology



SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple were received on the 30th November 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue

Samples described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Purple

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-62.9
37% Formaldehyde (CAS: 50-00-0)	-43.9
30% Hydrogen peroxide (CAS: 7722-84-1)	-2.3

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

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SATRA Reference: CHM0305690/2049/LH/B
Date: 13th January 2021

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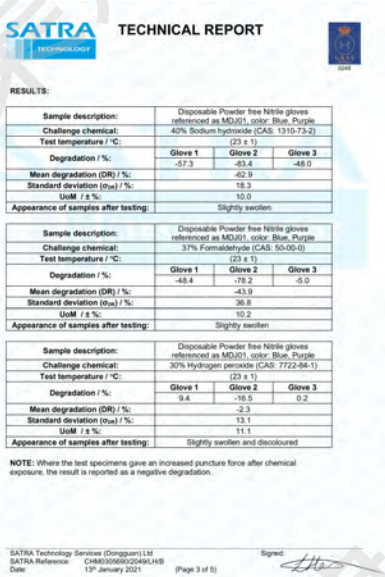

SATRA TECHNOLOGY

TECHNICAL REPORT

RESULTS:

Sample description:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-57.3	-63.4	-48.0
Mean degradation (DR) / %:	-62.9		
Standard deviation (σ_{DR}) / %:	18.3		
UoM / ± %:	10.0		
Appearance of samples after testing:	Slightly swollen		

Sample description:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-48.4	-78.2	-5.0
Mean degradation (DR) / %:	-43.9		
Standard deviation (σ_{DR}) / %:	36.8		
UoM / ± %:	10.2		
Appearance of samples after testing:	Slightly swollen		

Sample description:	Disposable Powder free Nitrile gloves referenced as MDJ01, color: Blue, Purple		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	9.4	-16.5	0.2
Mean degradation (DR) / %:	-2.3		
Standard deviation (σ_{DR}) / %:	13.1		
UoM / ± %:	11.1		
Appearance of samples after testing:	Slightly swollen and discoloured		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305690/2049/LH/B
Date: 13th January 2021

Signed:

SATRA TECHNOLOGY

TECHNICAL REPORT

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305690/2049/LH/B
Date: 13th January 2021

Signed:

SATRA TECHNOLOGY

TECHNICAL REPORT

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305690/2049/LH/B
Date: 13th January 2021

Signed:

福建集翔

Fujian Jixiang

examining report PVC

EN ISO21420 ISO374 PVC

SATRA TECHNOLOGY

SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nancheng District, Dongguan City
Guangdong Province, China
Tel: +86-(0) 769 22888220
email: info@satra.com

Customer details: Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Ceiwu Town,
Changting County,
Fujian Province,
China

SATRA reference: CHT0305550 /2048
Your reference: MPVC01
Date of report: 23 December 2020
Samples received: 27 November 2020
Date(s) work carried out: 01-18 December 2020

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak test on Disposable Powder free PVC gloves referenced as MPVC01, colour: White, size: 6, 7, 8

Conditions of Issue:

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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

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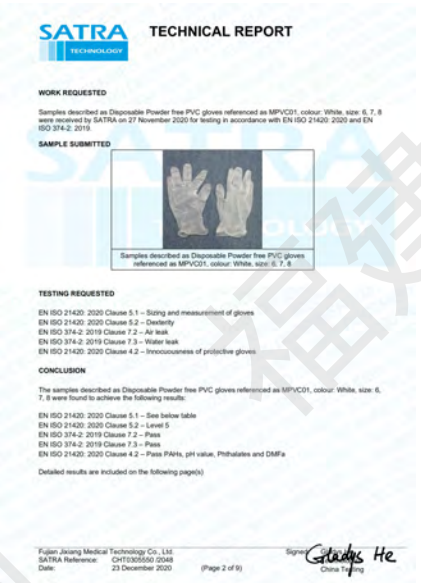

SATRA TECHNOLOGY — TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder free PVC gloves referenced as MPVC01, colour: White, size: 6, 7, 8 were received by SATRA on 27 November 2020 for testing in accordance with EN ISO 21420: 2020 and EN ISO 374-2: 2019.

SAMPLE SUBMITTED

Samples described as Disposable Powder free PVC gloves referenced as MPVC01, colour: White, size: 6, 7, 8

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 PVC gloves referenced as MPVC01, colour: White, size: 6, 7, 8 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, Phthalates and DMFa

Detailed results are included on the following page(s)

Fujian Jixiang Medical Technology Co., Ltd.
SATRA Reference: CHT0305550 /2048
Date: 23 December 2020
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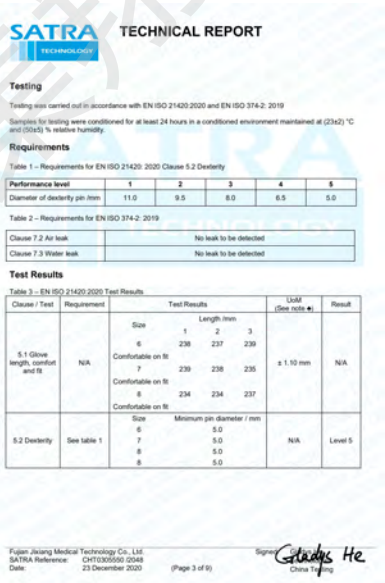
Signed: Gladys He, China Testing



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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	± 1.10 mm	N/A
		6 Comfortable on fit	238	237	239		
		7 Comfortable on fit	239	238	235		
		8 Comfortable on fit	234	234	237		
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				
		9	5.0				

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Date: 23 December 2020
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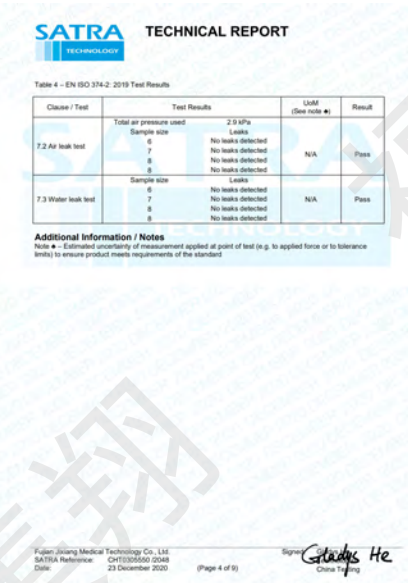

SATRA TECHNOLOGY — TECHNICAL REPORT

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

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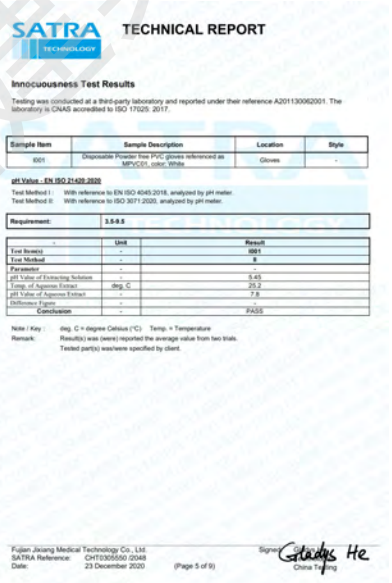

SATRA TECHNOLOGY — TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A201130062001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
6001	Disposable Powder free PVC gloves referenced as MPVC01, color: White	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)	-	6001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.45
Temp. of Aqueous Extract	deg. C	25.2
pH Value of Aqueous Extract	-	7.8
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.
Tested part(s) was/were specified by client.

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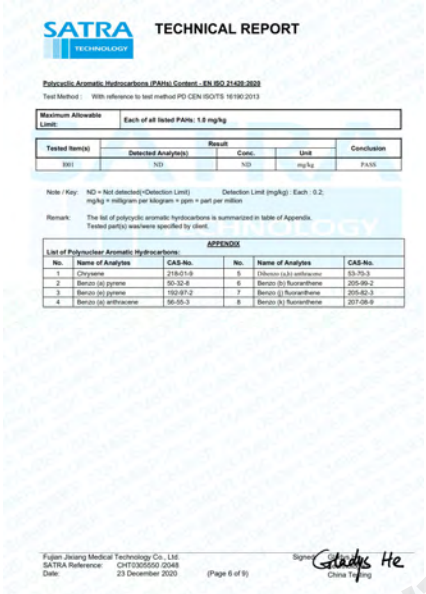
EN ISO21420 ISO374 PVC



SATRA TECHNOLOGY

TECHNICAL REPORT

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 hydrocarbons is summarized in table of Appendix.
Tested part(s) was/were specified by client.

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

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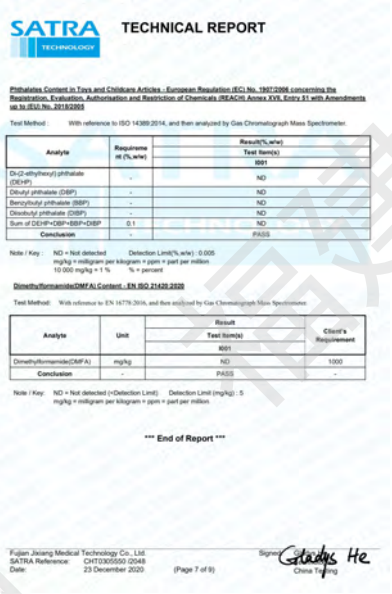

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TECHNICAL REPORT

Phthalates Content in Toys and Childcare Articles - European Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII, Entry 51 with Amendments up to (EU) No. 2018/2005

Test Method : With reference to ISO 14389:2014, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Requirement (% w/w)	Result(% w/w) Test Item(s)
		I001
Di-(2-ethylhexyl) phthalate (DEHP)	-	ND
Dibutyl phthalate (DBP)	-	ND
Benzylbutyl phthalate (BBP)	-	ND
Diisobutyl phthalate (DIBP)	-	ND
Sum of DEHP+DBP+BBP+DIBP	0.1	ND
Conclusion	-	PASS

Note / Key : ND = Not detected Detection Limit(% w/w) : 0.005
mg/kg = milligram per kilogram = ppm = part per million
10,000 mg/kg = 1 % % = percent

Dimethylformamide(DMF) Al Content - EN ISO 21420:2020

Test Method: With reference to EN 16779:2016, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result Test Item(s)	Client's Requirement
		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 ***

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

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Signed: Gladys He
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EN ISO21420 ISO374 -3 PVC

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Customer details: SATRA Technology Services (Dongguan) Ltd
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DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305689/2049/LC/A
Your reference: CHT0305550
Date of report: 15th January 2021
Samples received: 30th November 2020
Date(s) work carried out: 16th December 2020 to 15th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Cewu Town,
Changting County,
Fujian Province,
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powder free PVC gloves referenced as MPVC01

Conditions of Issue:

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

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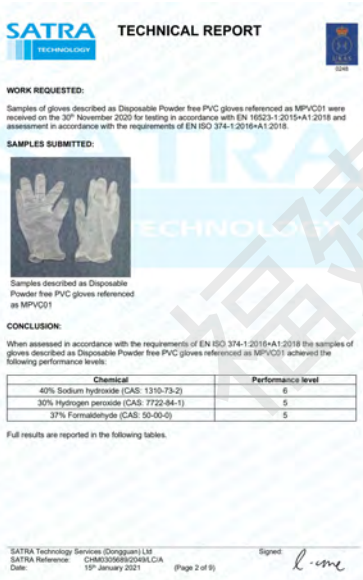
A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (U(xM)) 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: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology



SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powder free PVC gloves referenced as MPVC01 were received on the 30th November 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:

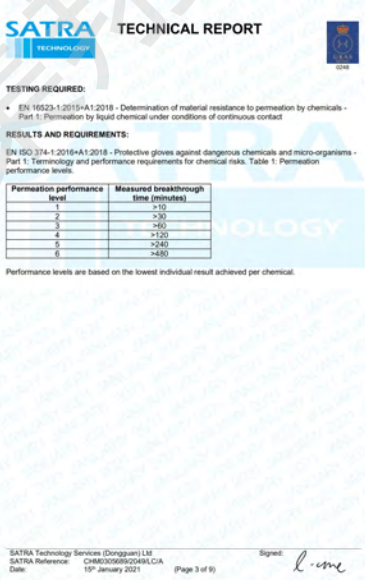
Samples described as Disposable Powder free PVC gloves referenced as MPVC01

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powder free PVC gloves referenced as MPVC01 achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	5
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.



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TECHNICAL REPORT

TESTING REQUIRED:

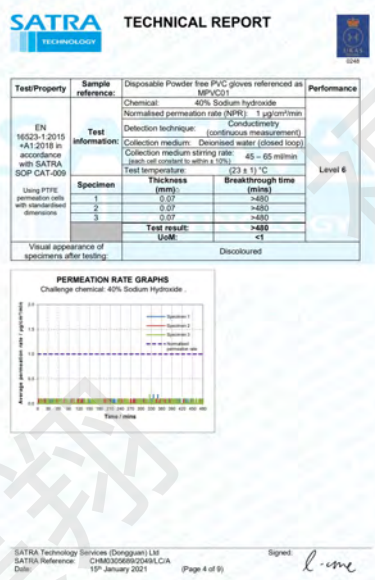
- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

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

Performance levels are based on the lowest individual result achieved per chemical.

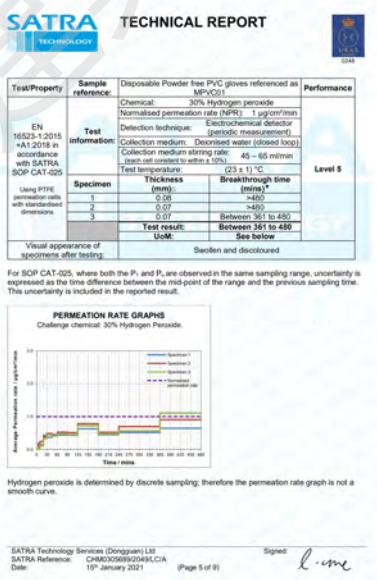


SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powder free PVC gloves referenced as MPVC01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical:	40% Sodium hydroxide	Level 6
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Conductimetry (continuous measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)	
	1	0.07	>480	
	2	0.07	>480	
	3	0.07	>480	
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:		Discoloured		

PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide.



SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powder free PVC gloves referenced as MPVC01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical:	30% Hydrogen peroxide	Level 5
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	Electrochemical detector (periodic measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell constant to within ± 10%)	45 – 65 ml/min	
		Test temperature:	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1	0.08	>480	
	2	0.07	>480	
	3	0.07	Between 361 to 480	
		Test result:	Between 361 to 480	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P_1 and P_2 are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

PERMEATION RATE GRAPHS
Challenge chemical: 30% Hydrogen Peroxide.

Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

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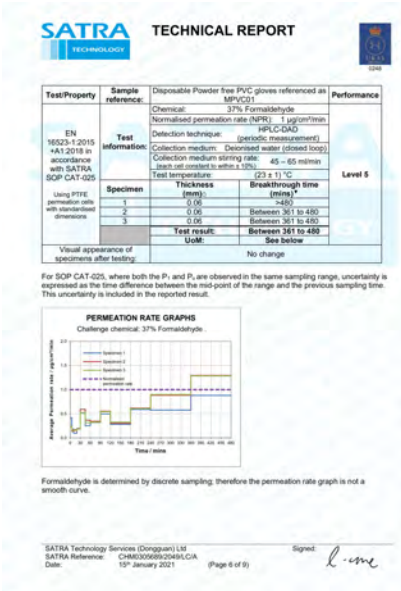
EN ISO21420 ISO374 -3 PVC



SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powder free PVC gloves referenced as MPVC01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical:	37% Formaldehyde	Level 5
		Normalised permeation rate (NPR):	1 µg/cm²/min	
		Detection technique:	HPLC-DAD (periodic measurement)	
		Collection medium:	Deionised water (closed loop)	
		Collection medium stirring rate: (each cell corsited to within ± 10%)	45 – 65 ml/min	
		Test temperature	(23 ± 1) °C	
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1	0.06	>480	
	2	0.06	Between 361 to 480	
	3	0.06	Between 361 to 480	
		Test result:	Between 361 to 480	
		UoM:	See below	
Visual appearance of specimens after testing:		No change		

For SOP CAT-025, where both the P_1 and P_2 are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

Formaldehyde is determined by discrete sampling, therefore the permeation rate graph is not a smooth curve.

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○ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

* Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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EN ISO21420 ISO374 -4 PVC

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DONGGUAN CITY
Guangdong Province
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523079

SATRA reference: CHM0305689/2049/LC (B)
Your reference: CHT0305550
Date of report: 15th January 2021
Samples received: 30th November 2020
Date(s) work carried out: 8th to 13th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Cewu Town,
Changting County,
Fujian Province,
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powder free PVC gloves referenced as MPVC01.

Conditions of Issue:

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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 (U#M) 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: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

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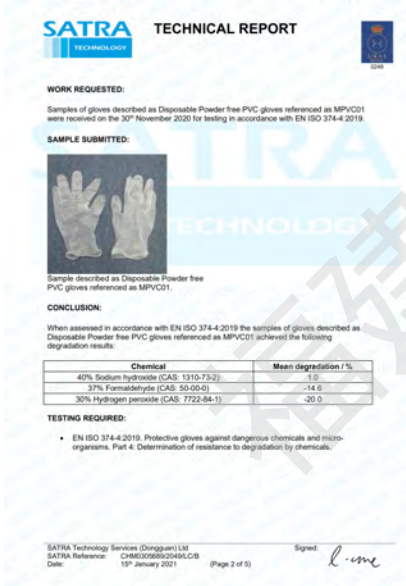

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powder free PVC gloves referenced as MPVC01 were received on the 30th November 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Sample described as Disposable Powder free PVC gloves referenced as MPVC01.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powder free PVC gloves referenced as MPVC01 achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	1.0
37% Formaldehyde (CAS: 50-00-0)	-14.6
30% Hydrogen peroxide (CAS: 7722-84-1)	-20.0

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

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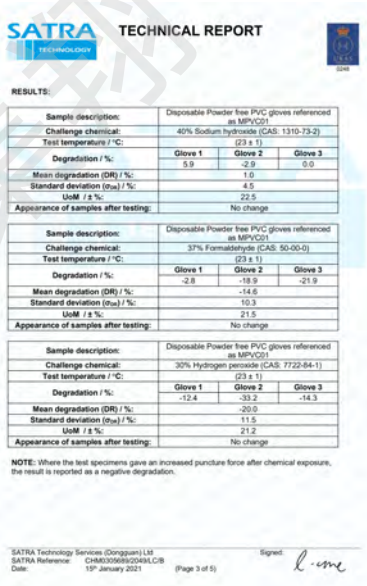

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RESULTS:

Sample description:	Disposable Powder free PVC gloves referenced as MPVC01		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	5.9	-2.9	0.0
Mean degradation (DR) / %:	1.0		
Standard deviation (σ_{DR}) / %:	4.5		
UoM ± %:	22.5		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder free PVC gloves referenced as MPVC01		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-2.8	-18.9	-21.9
Mean degradation (DR) / %:	-14.6		
Standard deviation (σ_{DR}) / %:	10.3		
UoM ± %:	21.5		
Appearance of samples after testing:	No change		

Sample description:	Disposable Powder free PVC gloves referenced as MPVC01		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-12.4	-33.2	-14.3
Mean degradation (DR) / %:	-20.0		
Standard deviation (σ_{DR}) / %:	11.5		
UoM ± %:	21.2		
Appearance of samples after testing:	No change		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

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Date: 15th January 2021

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SATRA Reference: CHM0305689/2049/LC/B
Date: 15th January 2021

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SATRA TECHNOLOGY

Customer details: Fujian Jixiang Medical Technology Co., Ltd. No. 29 Tingzhou Avenue, Ceeru Town, Changting County, Fujian Province, China

SATRA reference: CHT0305549 /2048
Your reference: MRJ01
Date of report: 23 December 2020
Samples received: 27 November 2020
Date(s) work carried out: 01-18 December 2020

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak test on Disposable Powdered Latex Gloves referenced as MRJ01, Colour: White, size: 6, 7

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.

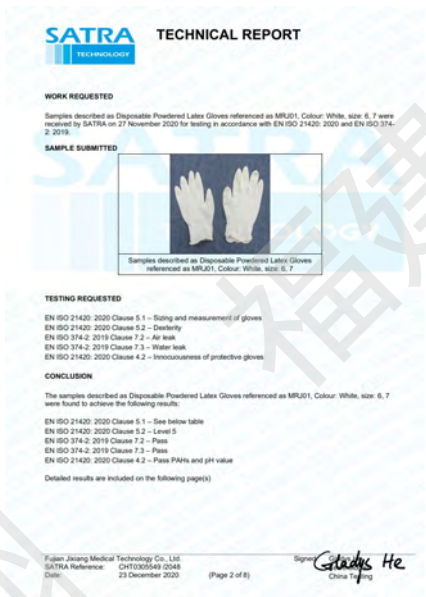
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

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

(Page 1 of 8)



SATRA TECHNOLOGY **TECHNICAL REPORT**

WORK REQUESTED

Samples described as Disposable Powdered Latex Gloves referenced as MRJ01, Colour: White, size: 6, 7 were received by SATRA on 27 November 2020 for testing in accordance with EN ISO 21420: 2020 and EN ISO 374-2: 2019.

SAMPLE SUBMITTED

Samples described as Disposable Powdered Latex Gloves referenced as MRJ01, Colour: White, size: 6, 7

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 Powdered Latex Gloves referenced as MRJ01, Colour: White, size: 6, 7 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 and pH value

Detailed results are included on the following page(s)

Fujian Jixiang Medical Technology Co., Ltd.
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Date: 23 December 2020
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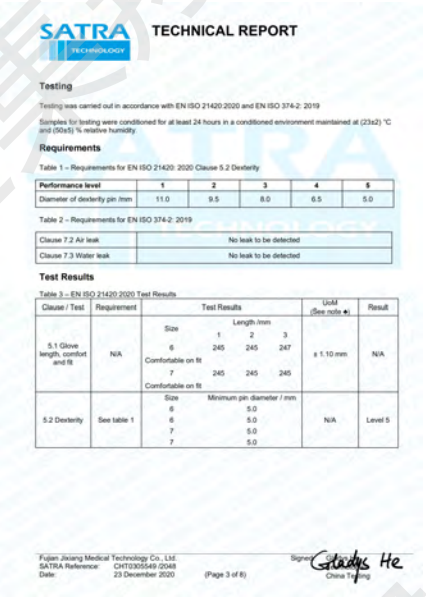
Signed: Gladys He, China Testing



SATRA TECHNOLOGY **TECHNICAL REPORT**

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	± 1.10 mm	N/A
		6	245	245	247		
		Comfortable on fit					
		7	245	245	245		
		Comfortable on fit					
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		6	5.0				
		7	5.0				
		7	5.0				

Fujian Jixiang Medical Technology Co., Ltd.
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Date: 23 December 2020
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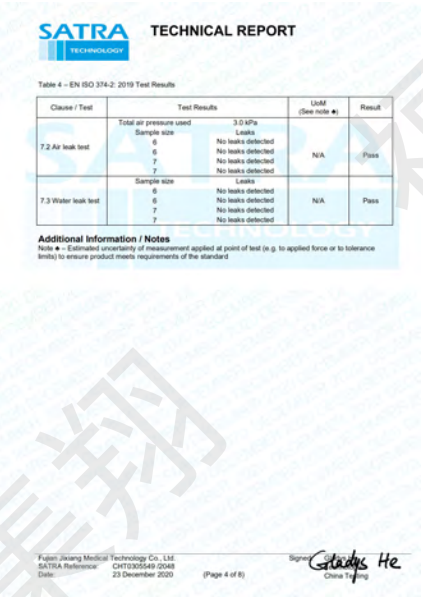

SATRA TECHNOLOGY **TECHNICAL REPORT**

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	3.0 kPa	N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	7	No leaks detected		
7.3 Water leak test	Sample size	Leaks	N/A	Pass
	6	No leaks detected		
	6	No leaks detected		
	7	No leaks detected		
	7	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

Fujian Jixiang Medical Technology Co., Ltd.
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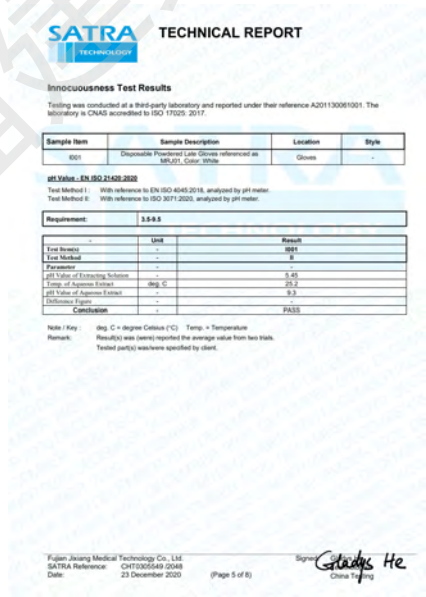

SATRA TECHNOLOGY **TECHNICAL REPORT**

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A201130061001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
6001	Disposable Powdered Latex Gloves referenced as MRJ01, Color: White	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)	-	6001
Test Method	-	II
Parameter	-	-
pH Value of Extracting Solution	-	5.45
Temp. of Aqueous Extract	deg. C	25.2
pH Value of Aqueous Extract	-	9.3
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.
Tested part(s) was/were specified by client.

Fujian Jixiang Medical Technology Co., Ltd.
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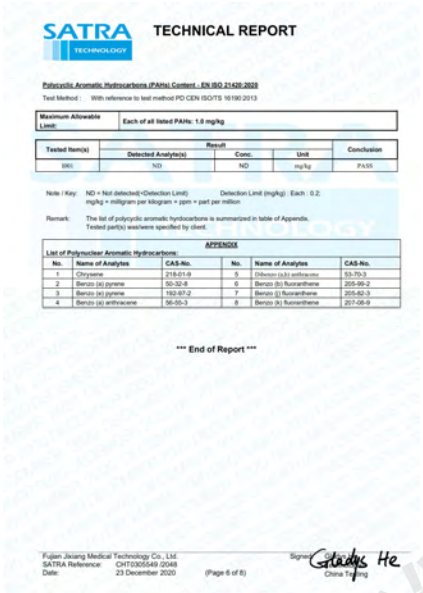
examining report Latex

EN ISO21420 ISO374 乳胶



SATRA TECHNOLOGY

TECHNICAL REPORT

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	
1001	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 hydrocarbons is summarized in table of Appendix.
Tested part(s) was/were specified by client.

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

*** End of Report ***

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Signed: Gretadys He
China Testing

SATRA TECHNOLOGY

TECHNICAL REPORT

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

Fujian Jixiang Medical Technology Co., Ltd.
SATRA Reference: CHT0305549 /2048
Date: 23 December 2020 (Page 7 of 8)

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SATRA TECHNOLOGY

TECHNICAL REPORT

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

Fujian Jixiang Medical Technology Co., Ltd.
SATRA Reference: CHT0305549 /2048
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China Testing

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EN ISO21420 ISO374 -3 乳胶

SATRA TECHNOLOGY

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Customer details: SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden
Hongwei Road
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079

SATRA reference: CHM0305686/2049/LC/A
Your reference: CHT0305549
Date of report: 12th January 2021
Samples received: 30th November 2020
Date(s) work carried out: 16th December 2020 to 12th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Fujian Jixiang Medical Technology Co., Ltd
No. 29 Tingzhou Avenue,
Cewu Town,
Changling County,
Fujian Province,
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Powdered Latex Gloves referenced as MRJ01

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.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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: Lucy Gove
Position: Technologist
Department: Chemical & Analytical Technology

(Page 1 of 10)

SATRA Technology Centre Ltd (a subsidiary of SATRA). Registered in England No. 3856256 at the above address.

SATRA TECHNOLOGY

TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powdered Latex Gloves referenced as MRJ01 were received on the 30th November 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:

Samples described as Disposable Powdered Latex Gloves referenced as MRJ01

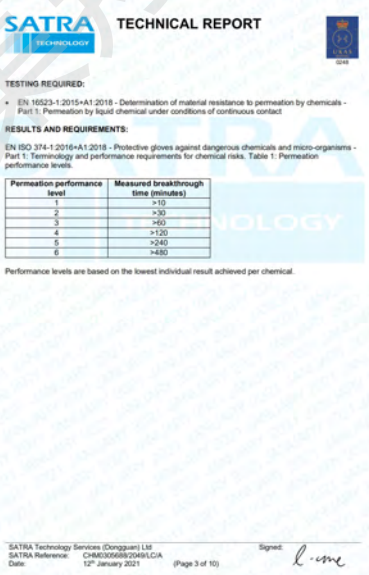
CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Powdered Latex Gloves referenced as MRJ01 achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	Inhomogeneous
30% Hydrogen peroxide (CAS: 7722-84-1)	2
37% Formaldehyde (CAS: 50-00-0)	Inhomogeneous

Full results are reported in the following tables.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021
(Page 2 of 10)
Signed:



SATRA TECHNOLOGY

TECHNICAL REPORT

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

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

Performance levels are based on the lowest individual result achieved per chemical.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021
(Page 3 of 10)
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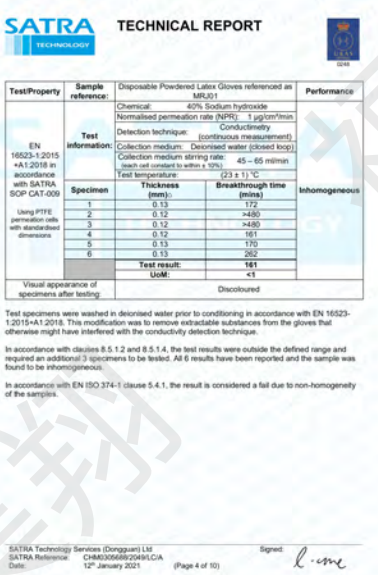

SATRA TECHNOLOGY

TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powdered Latex Gloves referenced as MRJ01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009	Test information:	Chemical: 40% Sodium hydroxide		
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)	Breakthrough time (mins)	Inhomogeneous
Using PTFE permeation cells with standardised dimensions	1	0.13	172	
	2	0.12	>480	
	3	0.12	>480	
	4	0.12	161	
	5	0.13	170	
	6	0.13	262	
		Test result:	161	
		UoM:	<1	
Visual appearance of specimens after testing:		Discoloured		

Test specimens were washed in deionised water prior to conditioning in accordance with EN 16523-1:2015+A1:2018. This modification was to remove extractable substances from the gloves that otherwise might have interfered with the conductivity detection technique.

In accordance with clauses 8.5.1.2 and 8.5.1.4, the test results were outside the defined range and required an additional 3 specimens to be tested. All 6 results have been reported and the sample was found to be inhomogeneous.

In accordance with EN ISO 374-1 clause 5.4.1, the result is considered a fail due to non-homogeneity of the samples.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021
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Signed:

SATRA TECHNOLOGY

TECHNICAL REPORT

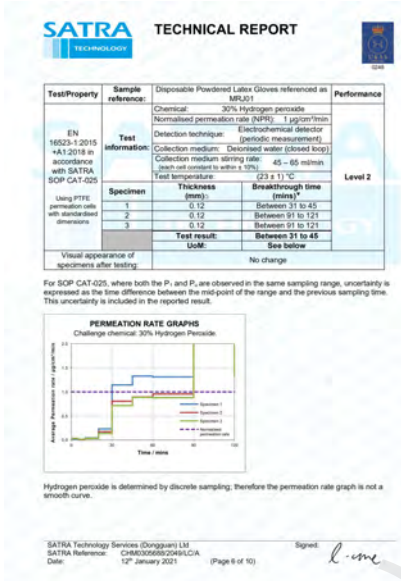
PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide .

PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide .

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021
(Page 5 of 10)
Signed:

examining report Latex

EN ISO21420 ISO374-3 乳胶



SATRA TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powdered Latex Gloves referenced as MRJ01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 30% Hydrogen peroxide		
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%): 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		Level 2
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1	0.12	Between 31 to 45	
	2	0.12	Between 91 to 121	
	3	0.12	Between 91 to 121	
		Test result:	Between 31 to 45	
		UoM:	See below	
Visual appearance of specimens after testing:		No change		

For SOP CAT-025, where both the P_1 and P_2 are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

PERMEATION RATE GRAPHS

Challenge chemical: 30% Hydrogen Peroxide

Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

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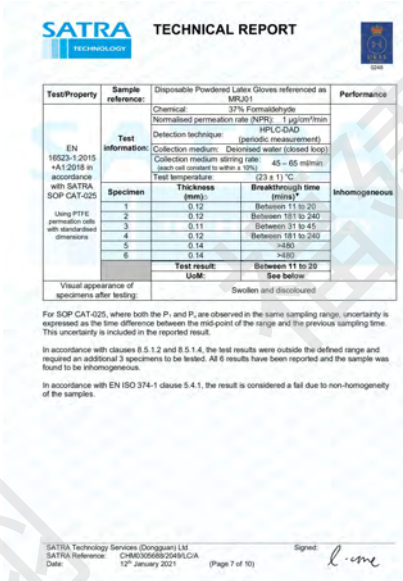

SATRA TECHNICAL REPORT

Test/Property	Sample reference:	Disposable Powdered Latex Gloves referenced as MRJ01		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025	Test information:	Chemical: 37% Formaldehyde		
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%): 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		Inhomogeneous
Using PTFE permeation cells with standardised dimensions	Specimen	Thickness (mm):	Breakthrough time (mins)*	
	1	0.12	Between 11 to 20	
	2	0.12	Between 181 to 240	
	3	0.11	Between 31 to 45	
	4	0.12	Between 181 to 240	
	5	0.14	>480	
	6	0.14	>480	
		Test result:	Between 11 to 20	
		UoM:	See below	
Visual appearance of specimens after testing:		Swollen and discoloured		

For SOP CAT-025, where both the P_1 and P_2 are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

In accordance with clauses 8.5.1.2 and 8.5.1.4, the test results were outside the defined range and required an additional 3 specimens to be tested. All 6 results have been reported and the sample was found to be inhomogeneous.

In accordance with EN ISO 374-1 clause 5.4.1, the result is considered a fail due to non-homogeneity of the samples.

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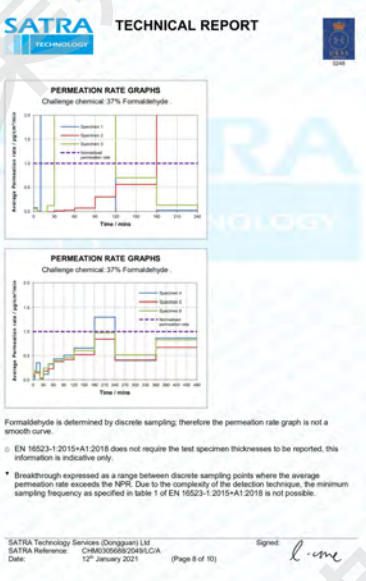
SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021 (Page 7 of 10)



SATRA TECHNICAL REPORT

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde

Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

- EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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SATRA Reference: CHM0305689/2049/LC/A
Date: 12th January 2021 (Page 8 of 10)

SATRA TECHNICAL REPORT

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

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SATRA TECHNICAL REPORT

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

SATRA Technology Services (Dongguan) Ltd Signed:
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Date: 12th January 2021 (Page 10 of 10)

福建集翔

Fujian Jixiang

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EN ISO21420 ISO374-4 乳胶

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Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
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Customer details:	SATRA Technology Services (Dongguan) Ltd Unit 110, Xinzhongyin Garden Hongwei Road Xiping, Nancheng District DONGGUAN CITY Guangdong Province China 523079	SATRA reference:	CHM0305688/2049/LC/B
		Your reference:	CHT0305549
		Date of report:	12th January 2021
		Samples received:	30th November 2020
		Date(s) work carried out:	23rd December 2020 to 5th January 2021

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Fujian Jixiang Medical Technology Co., Ltd.
No. 29 Tingzhou Avenue,
Cewu Town,
Changting County,
Fujian Province,
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Powdered Latex Gloves referenced as MRJ01.

Conditions of Issue:

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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: Lucy Cove
Position: Technologist
Department: Chemical & Analytical Technology

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TECHNICAL REPORT

WORK REQUESTED:

Samples of gloves described as Disposable Powdered Latex Gloves referenced as MRJ01 were received on the 30th November 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:

Sample described as Disposable Powdered Latex Gloves referenced as MRJ01.

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Powdered Latex Gloves referenced as MRJ01 achieved the following degradation results:

Chemical	Mean degradation / %
40% Sodium hydroxide (CAS: 1310-73-2)	-19.6
37% Formaldehyde (CAS: 50-00-0)	-18.6
30% Hydrogen peroxide (CAS: 7722-84-1)	21.3

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

SATRA Technology Services (Dongguan) Ltd
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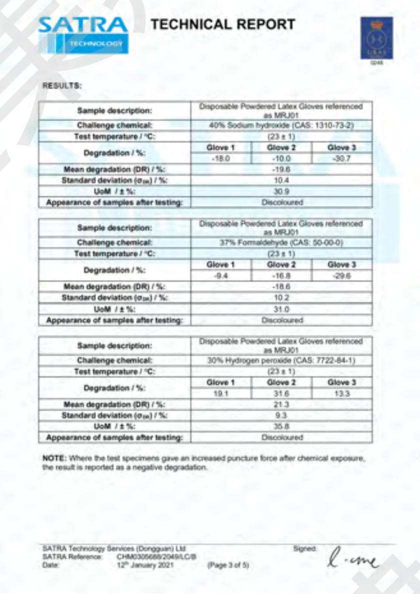

TECHNICAL REPORT

RESULTS:

Sample description:	Disposable Powdered Latex Gloves referenced as MRJ01		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-18.0	-10.0	-30.7
Mean degradation (DR) / %:	-19.6		
Standard deviation (σ_{DR}) / %:	10.4		
UoM / ± %:	30.9		
Appearance of samples after testing:	Discoloured		

Sample description:	Disposable Powdered Latex Gloves referenced as MRJ01		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	-9.4	-16.8	-29.6
Mean degradation (DR) / %:	-18.6		
Standard deviation (σ_{DR}) / %:	10.2		
UoM / ± %:	31.0		
Appearance of samples after testing:	Discoloured		

Sample description:	Disposable Powdered Latex Gloves referenced as MRJ01		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	**Glove 1**	**Glove 2**	**Glove 3**
	19.1	31.6	13.3
Mean degradation (DR) / %:	21.3		
Standard deviation (σ_{DR}) / %:	9.3		
UoM / ± %:	35.8		
Appearance of samples after testing:	Discoloured		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305688/2049/LC/B
Date: 12th January 2021 (Page 3 of 5)

TECHNICAL REPORT

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305688/2049/LC/B
Date: 12th January 2021 (Page 4 of 5)

TECHNICAL REPORT

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

SATRA Technology Services (Dongguan) Ltd
SATRA Reference: CHM0305688/2049/LC/B
Date: 12th January 2021 (Page 5 of 5)

欧盟委员会法规（EC)1935/2004

GST

Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 1 of 7

Applicant : Fujian Jixiang Medical Technology Co., Ltd.
客户/申请商 : 福建集翔医疗科技有限公司
Address : No. 29 Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, China
地址 : 福建省长汀县策武镇汀州大道南路 29 号
Report on the submitted sample(s) said to be:
委托检验的样品及申请者对样品的说明如下：
Sample(s) Name : NITRILE GLOVES
样品名称 : 丁腈手套
Sample(s) received date : Dec 25, 2020
样品接收日期 : 2020-12-25
Testing period : From Dec 05, 2020 to Jan 06, 2021
样品测试周期 : 2020-12-25 至 2021-01-06

Test Request 测试要求	Conclusion 结论
(1) As specified by client, to determine the Overall Migration in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs. 依据客户要求，参考欧盟委员会法规(EC) No 1935/2004 和欧洲委员会决议 AP(2004)4 与食品接触的橡胶材料，对委托样品进行全迁移测试。	Pass 合格
(2) As specified by client, to determine the Specific Migration of Primary Aromatic Amine in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs. 依据客户要求，参考欧盟委员会法规(EC) No 1935/2004 和欧洲委员会决议 AP(2004)4 与食品接触的橡胶材料，对委托样品进行初级芳香胺特定迁移测试。	Pass 合格

Ben Mao
Technical Manager
技术经理

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Shenzhen General Standard Testing Services Co.,Ltd
2/F&3/F-5/F East Wing,Building C10,ZheCai 2nd industrial zone,Xixiang Street,Bao'an District, Shenzhen, Guangdong, China
Tel: 86-0755-26307999 Website: www.gst-lab.com

GST

Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 2 of 7

Test Request 测试要求
(3) As specified by client, to determine the Specific Migration of Nitrosamines and Nitrosatable substances in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and Council of Europe Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs.
依据客户要求，参考欧盟委员会法规(EC) No. 1935/2004 和欧洲委员会决议AP(2004)4与食品接触的橡胶材料，对委托样品进行亚硝胺和亚硝基化合物特定迁移测试。

Conclusion 结论
Pass
合格

Photograph(s) of Sample
样品照片

GST authenticate the photo on original report only
此照片仅限于随 GST 正本报告使用

Specimen Description:
样品描述:

No. 序号	Test part(s) name 测试部件名称
1	Purple gloves (Material: Butyronitrile) 紫色手套（材质：丁腈）

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Shenzhen General Standard Testing Services Co.,Ltd
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Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 3 of 7

Results:
结果：
(1) Overall Migration- European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .
全面迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料
Test Method: With reference to EN 1186-1:2002 & EN 1186-2:2002 & EN 1186-14:2002
测试方法： 参考 EN 1186-1:2002 & EN 1186-2:2002 & EN 1186-14:2002

模拟液	Unit 单位	Time 时间	Temperature 温度	MDL 方法检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果 1
3%(w/v) acetic acid in aqueous solution 3%(w/v) 乙酸溶液	mg/dm²	2H	25℃	3	10	4.48
10% (v/v)ethanol in aqueous solution 10% (v/v)乙醇溶液	mg/dm²	2H	25℃	3	10	3.34
20% (v/v) ethanol in aqueous solution 20% (v/v)乙醇溶液	mg/dm²	2H	25℃	3	10	4.34
50% (v/v) ethanol in aqueous solution 50% (v/v)乙醇溶液	mg/dm²	2H	25℃	3	10	5.53

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2/F&3/F-5/F East Wing,Building C10,ZheCai 2nd industrial zone,Xixiang Street,Bao'an District, Shenzhen, Guangdong, China
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Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 4 of 7

(2) Specific Migration of Primary Aromatic Amine- European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .
初级芳香胺特定迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料
Test Method: With reference to BS EN 13130-1:2004 & DIN 55610:1986
测试方法： 参考 BS EN 13130-1:2004 & DIN 55610:1986
Test condition: 3% (w/v)acetic acid in aqueous solution, 25℃, 2hours
测试条件： 3% (w/v)乙酸溶液, 25℃, 2 小时
Test Instrument: Gas Chromatography-Mass Spectrometer (GC-MS)
测试仪器： 气相色谱-质谱联用仪(GC-MS)

Test item(s) 测试项目	Unit 单位	MDL 方法检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果 1
Specific Migration of Primary Aromatic Amine(PAA) 初级芳香胺特定迁移（PAA）	mg/kg	0.01	Not Detected 不得检出	N.D.

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Tel: 86-0755-26307999 Website: www.gst-lab.com

GST

Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 5 of 7

(3) Specific Migration of Nitrosamines and Nitrosatable substances - European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .
亚硝胺和亚硝基化合物特定迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料
Test Method: With reference to BS EN 13130-1:2004&BS EN 12868:2017
测试方法： With reference to BS EN 13130-1:2004&BS EN 12868:2017
Test condition: 3% (w/v)acetic acid in aqueous solution, 40℃, 24hours
测试条件： 3% (w/v)乙酸溶液, 40℃, 24 小时
Test Instrument: Liquid Chromatography-Mass Spectrometer (LC-MS)
测试仪器： 液相色谱-质谱联用仪

Test item(s) 测试项目	Unit 单位	MDL 方法检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果 1
Migration of N-Nitrosamines 亚硝胺迁移	mg/kg	0.01	0.01	N.D.
Migration of N- Nitrosatable Substances 亚硝基酰化合物迁移	mg/kg	0.1	0.1	N.D.

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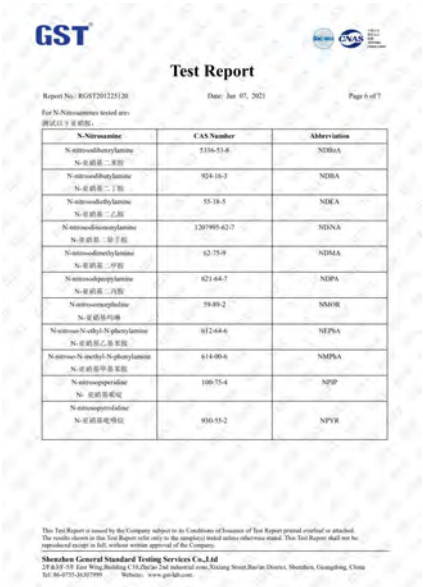
Shenzhen General Standard Testing Services Co.,Ltd
2/F&3/F-5/F East Wing,Building C10,ZheCai 2nd industrial zone,Xixiang Street,Bao'an District, Shenzhen, Guangdong, China
Tel: 86-0755-26307999 Website: www.gst-lab.com

欧盟委员会法规（EC)1935/2004



GST

Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 6 of 7

For N-Nitrosamines tested are:

N-Nitrosamine	CAS Number	Abbreviation
N-nitrosodibutylamine	5336-53-8	NDBzA
N-nitrosodibutylamine	924-16-3	NDBA
N-nitrosodiethylamine	55-18-5	NDEA
N-nitrosodiisononylamine	1207995-62-7	NDINA
N-nitrosodimethylamine	62-75-9	NDMA
N-nitrosodipropylamine	621-64-7	NDPA
N-nitrosomorpholine	59-89-2	NMOR
N-nitroso-N-ethyl-N-phenylamine	612-64-6	NEPhA
N-nitroso-N-methyl-N-phenylamine	614-00-6	NMPhA
N-nitrosopiperidine	100-75-4	NPIP
N-nitrosopyrrolidine	930-55-2	NPYR

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Shenzhen General Standard Testing Services Co.,Ltd

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Test Report

Report No.: RGST201225120 Date: Jan 07, 2021 Page 7 of 7

Note 备注:

- mg/kg=milligram per kilogram
- mg/kg= 毫克每千克
- mg/dm² = milligram per square decimeter
- mg/dm² =毫克每平方分米
- N.D. =Not Detected (<MDL)
- N.D. =未检出（小于方法检测限）
- Specific Migration of Nitrosamines and Nitrosatable substances is not included in CNAS Accreditation scope.
- 亚硝胺和亚硝基胺化合物特定迁移不在CNAS认可范围内。

*** End of Report ***
报告结束

This Test Report is issued by the Company subject to its Conditions of Issuance of Test Report printed overleaf or attached. The results shown in this Test Report refer only to the sample(s) tested unless otherwise stated. This Test Report shall not be reproduced except in full, without written approval of the Company.

Shenzhen General Standard Testing Services Co.,Ltd

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统一社会信用代码
91350821MA34H3YN1G

营业执照
（副本）

副本编号：1-1

名　　称　福建集翔医疗科技有限公司
类　　型　有限责任公司
法定代表人　张秀秀
经营范围　一般项目：医学研究和试验发展；第一类医疗器械生产；第一类医疗器械销售；第二类医疗器械销售；塑料制品制造；塑料制品销售；医护人员防护用品批发；医护人员防护用品零售；专用化学产品销售（不含危险化学品）；服装服饰批发；鞋帽批发；医科纺织加工；针织或钩针编织物及其制品制造；劳动保护用品生产；特种劳动防护用品生产；服饰制造；针纺织品及原料销售；通讯设备销售；电子产品销售；非金属矿及制品销售；棉、麻销售；化工产品销售（不含许可类化工产品）；石油制品销售（不含危险化学品）；供应链管理服务；国内贸易代理；国际货物运输代理；国内货物运输代理；普通货物仓储服务（不含危险化学品等需许可审批的项目）（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）
许可项目：第二类医疗器械生产；第三类医疗器械生产；第三类医疗器械经营；货物进出口；技术进出口（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以相关部门批准文件或许可证件为准）

注册资本　壹亿圆整
成立日期　2020年08月14日
营业期限　2020年08月14日 至 2050年08月13日
住　　所　福建省长汀县策武镇灯州大道南路29号

登记机关

2020 年 8 月 14 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn
市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告
国家市场监督管理总局监制

福建集翔医疗科技有限公司

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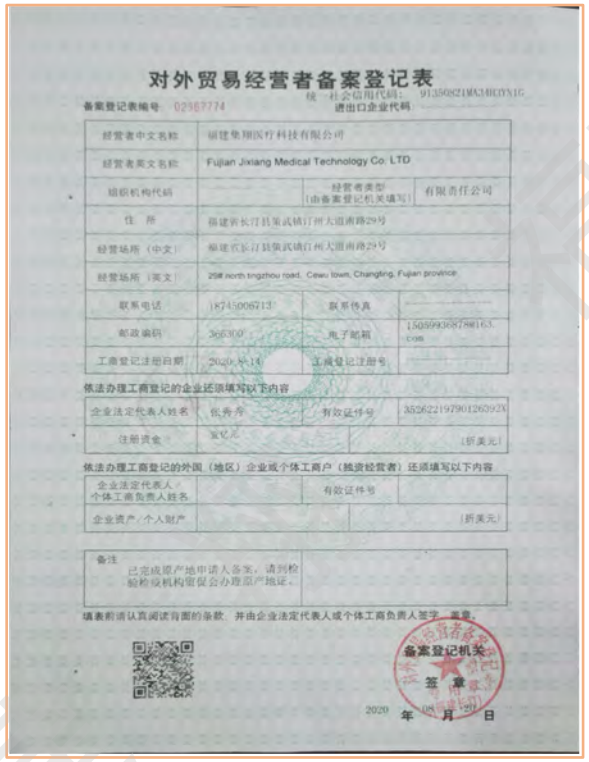

对外贸易经营者备案登记表

备案登记表编号：02567774　　进出口企业代码：

经营者中文名称	福建集翔医疗科技有限公司		
经营者英文名称	Fujian Jixiang Medical Technology Co. LTD		
组织机构代码		经营者类型（由备案登记机关填写）	有限责任公司
住　所	福建省长汀县策武镇汀州大道南路29号		
经营场所（中文）	福建省长汀县策武镇汀州大道南路29号		
经营场所（英文）	29# north tingzhou road, Cewu town, Changting, Fujian province		
联系电话	18745006713	联系传真	
邮政编码	366300	电子邮箱	1505993687@163.com
工商登记注册日期	2020.9.14	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	张秀秀	有效证件号	352622197901260928
注册资金	贰亿元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人/个体工商负责人姓名		有效证件号	
企业资产/个人财产			（折美元）

备注：已完成原产地申请人备案，请到检验检疫机构窗报公办理原产地证。

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关（签章）

2020 年 09 月 14 日

第二类医疗器械经营备案凭证

备案编号：陶龙食药监械经营备 20206041 号

企业名称	福建集翔医疗科技有限公司
法定代表人	张秀秀
企业负责人	张秀秀
经营方式	批发
住　所	福建省长汀县策武镇汀州大道南路 29 号
经营场所	福建省长汀县策武镇汀州大道南路 29 号
库房地址	福建省长汀县策武镇汀州大道南路 29 号 1#厂房
经营范围	《医疗器械分类目录》（2002 版）II 类：6820、6834、6864、6866。《医疗器械分类目录》（2017 版）II 类：06、07、08、14、16、18。

备案部门（公章）

备案日期：2020 年 09 月 14 日

Fiscal Year 2021

CERTIFICATE OF FDA REGISTRATION

This certifies that: **Fujian Jixiang Medical Technology Co.,Ltd.**

29 Tingzhou Avenue South Road, Cewu Town, Changting County,Longyan, FUJIAN, 366399, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food &Drug Administration, through from a 3rd party registrant.

Owner/Operator Number: 10078357

Device Listing#:

Listing No.	Code:	Proprietary Name:	Activities:
D422378	QLB	Nitrile inspection gloves latex examination gloves PVC inspection gloves	Manufacturer

will confirm that such registration remains effective upon request and presentation ofthis certificate until the end of the calendar year stated above, unless said registration is terminated afterissuance of this certificate. 3rd party registrant makes no other representations or warranties, nor does thiscertificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of thecertificate-holder's device or establishment by the U.S. Food and Drug Administration. 3rd party registrant assumes no liability to any person or entity in connection with the foregoing.

Pursuant to21 CFR 807.39, "Registration of a device establishment or assignment of a registration number doesnot in any way denote approval of the establishment or its products. Any representation that creates animpression of fficial approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S.Food andDrug Administration recognize a certificate of registration, U3rd party registrant is not affiliated with the U.S. Food and Drug Administration.

U.S. Agent
Contact Name: Peimei Ding
Address: 67 crestwick,Irvine,CA,92620 U.S.A
Phone: 1-9495727869
E-mail: peimeiding@yahoo.com

CERTIFIED PASS USA

Issued Date: Oct 26, 2020
Expiration Date: December 31, 2021

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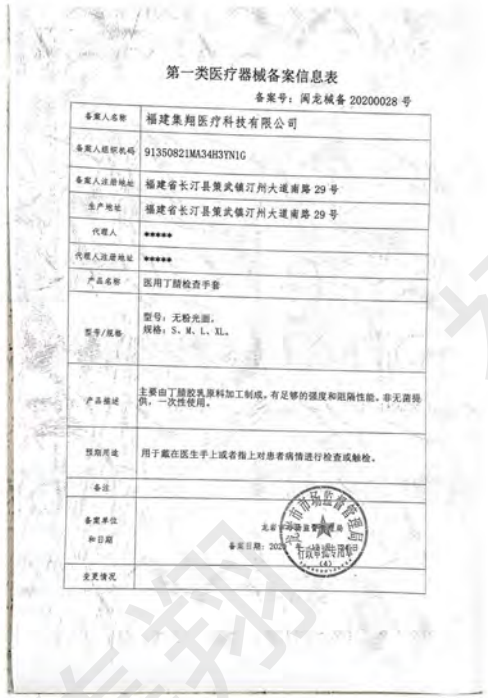
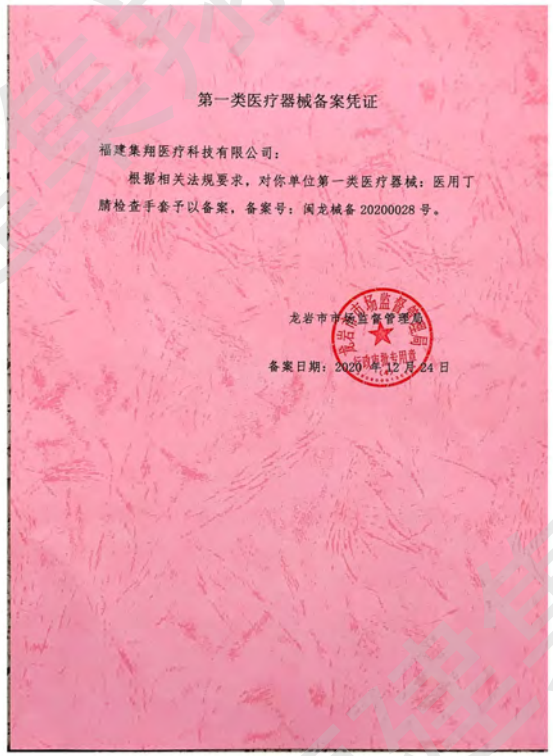


第一类医疗器械备案信息表

备案号：闽龙械备 20200028 号

备案人名称	福建集翔医疗科技有限公司
备案人组织机构代码	91350821MA34H3YN1G
备案人注册地址	福建省长汀县策武镇汀州大道南路 29 号
生产地址	福建省长汀县策武镇汀州大道南路 29 号
代理人	*****
代理人注册地址	*****
产品名称	医用丁腈检查手套
型号/规格	型号：无粉光面。 规格：S、M、L、XL。
产品描述	主要由丁腈胶乳原料加工制成。有足够的强度和阻隔性能。非无菌提供，一次性使用。
预期用途	用于戴在医生手上或者指上对患者病情进行检查或触检。
备注	
备案单位和日期	龙岩市市场监督管理局 备案日期：2020 年 12 月 24 日
变更情况	



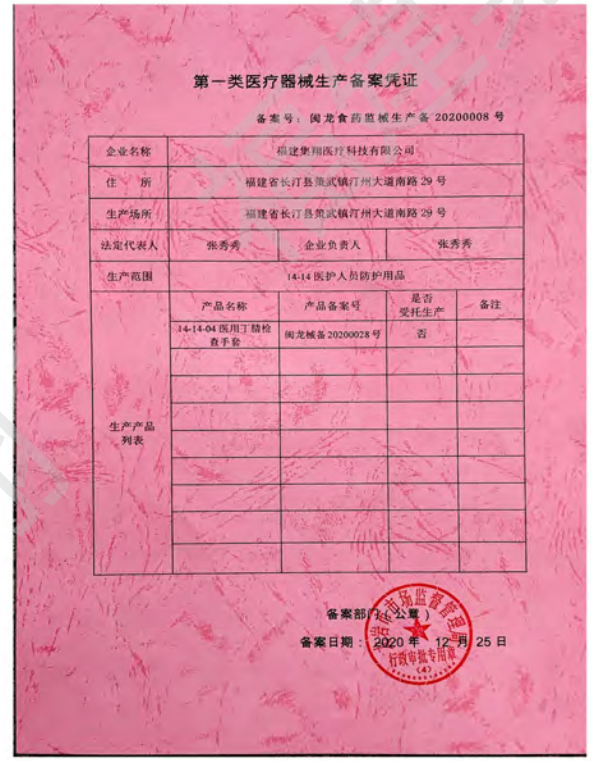
第一类医疗器械备案凭证

福建集翔医疗科技有限公司：

根据相关法规要求，对你单位第一类医疗器械：医用丁腈检查手套予以备案，备案号：闽龙械备 20200028 号。

龙岩市市场监督管理局

备案日期：2020 年 12 月 24 日



第一类医疗器械生产备案凭证

备案号：闽龙食药监械生产备 20200008 号

企业名称	福建集翔医疗科技有限公司		
住　所	福建省长汀县策武镇汀州大道南路 29 号		
生产场所	福建省长汀县策武镇汀州大道南路 29 号		
法定代表人	张秀秀	企业负责人	张秀秀
生产范围	14-14 医护人员防护用品		

生产产品列表	产品名称	产品备案号	是否受托生产	备注
	14-14-04 医用丁腈检查手套	闽龙械备 20200028 号	否	

备案部门（公章）

备案日期：2020 年 12 月 25 日

我们的资质

中华人民共和国
PEOPLE' S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：闽龙药监械出 20200001 号
Certificate NO.：Min Long Yao Jian Xie Chu No. 20200168

产品名称：医用丁腈检查手套
Product(s)： Nitrile Inspection Gloves For Medical Use

规格型号：无粉光面 S、M、L、XL
Model:Powder-free finish Small, medium, large, extra large

产品注册或备案凭证号：闽龙械备 20200028 号
Registration certificate(s)：Minlong Machinery No. 20200028

生产企业：福建集翔医疗科技有限公司
Manufacturer：Fujian Jixiang Medical Technology Co.LTD

生产企业住所：福建省长汀县策武镇辽州大道南路 29 号
Address of manufacturer:29# north tingzhou road ,Cewu town ,Changting ,Fujian Province

生产许可或备案凭证号：闽龙食药监械生产备 20200008 号
Manufacturing License(s)：Minlong Food and Drug Supervision and Mechanical production of 20200008

兹证明上述产品已准许在中国生产和销售。该产品出口不受限制。

This is to certify that the above products have been registered to be manufactured and sold in China. The exportation of the product(s) is not restricted.

证明有效日期至：2023 年 01 月 03 日
This certification valid until:2023-01-03

备注：
Remark:

2020 年 01 月 04 日
（出具单位盖章）

Producer： Fujian Jixiang Medical Technology Co.,Ltd.

amfori BSCI
Trade with purpose

Auditee :	Fujian Jixiang Medical Technology Co.,Ltd.
Audit Date From :	18/12/2020
Audit Date To :	18/12/2020
Expiry Date of the Audit :	Please refer to the producer profile in the amfori BSCI platform
Auditing Company :	TUEV NORD GROUP
Auditor's Name(s) :	Jack (Jun Yi) DONG(Lead)
Auditing Branch (If applicable) :	

amfori BSCI
Trade with purpose

This is an extract of the on line Audit Report.The complete report is available in the amfori BSCI Platform.
Access www.bsciplatform.org for entitled users only.

amfori BSCI www.bsciplatform.org Page 1/14

شهادة حلال

HALAL FOUNDATION CENTER

清真证书

MEMBER OF International Halal Integrity ALLIANCE 國際清真誠信聯盟成員

Halal Foundation Center Hong Kong 清真

Certificate No. 11503771337990 رقم شهادة الحلال

经严格的全面检查原料及相关证件，本证书证明以下产品经由清真食品监制中心 Halal Foundation Center 审核监督，不含清真禁忌成分，生产、加工过程符合清真法规要求，适合穆斯林使用。

المركز لمؤسسة الحلال (HFC) يعتمد فحص المكونات وتوثيقها ومدققيها يعلن بأن المنتج/المنتجات تحت الذكر حلال.

公司名称: 福建集翔医疗科技有限公司
اسم الشركة

公司地址: 福建省长汀县策武镇汀州大道南路29号
عنوان الشركة

生产地址: 福建省长汀县策武镇汀州大道南路29号
عنوان المصنع

认证产品: 见附页
اسم المنتجات

Mohammad Zubair

Hafiz Mohammad Zubair
哈菲日, 默罕默德, 祖贝爾
Director & Chief Executive Officer

2020-12-29 至 2023-12-28
Validity Period

Halal Foundation Center Hong Kong
www.halalfoundationcenter.org

شهادة حلال

HALAL FOUNDATION CENTER

清真证书

证书编码: 11503771337990
رقم شهادة الحلال

公司名称: 福建集翔医疗科技有限公司
工厂地址: 福建省长汀县策武镇汀州大道南路29号
品牌名: 集翔
产品列表:

1. 一次性PVC手套
2. 一次性丁腈手套

MEMBER OF International Halal Integrity ALLIANCE 國際清真誠信聯盟成員

Mohammad Zubair

Hafiz Mohammad Zubair
哈菲日, 默罕默德, 祖贝爾
Director & Chief Executive Officer

2020-12-29 至 2023-12-28
Validity Period

Halal Foundation Center Hong Kong
www.halalfoundationcenter.org

شهادة حلال

HALAL FOUNDATION CENTER

HALAL CERTIFICATE

MEMBER OF International Halal Integrity ALLIANCE 國際清真誠信聯盟成員

Certificate No. 11503771337990
رقم شهادة الحلال

HFC after examining , inspecting/ auditing and discussing the ingredients has declared the under mentioned products as halal.

المركز لمؤسسة الحلال (HFC) بعد فحص المكونات وتوثيقها ومناقشتها يعلن بأن المنتج/المنتجات تحت الذكر حلال.

Company Name: اسم الشركة	**Fujian Jixiang Medical Technology Co.,Ltd.**
Company Address: عنوان الشركة	**NO.29 South Road, Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, China**
Manufacturing Address: عنوان المصنع	**NO.29 South Road, Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, China**
Products: اسم المنتجات	**Refer to Attachment**

Mohammad Zubair

Hafiz Mohammad Zubair
Director & Chief Executive Officer

28 Dec, 2020 to 28 Dec, 2023
Validity Period

شهادة حلال

HALAL FOUNDATION CENTER

HALAL CERTIFICATE

Certificate No. 11503771337990
رقم شهادة الحلال

Company Name: **Fujian Jixiang Medical Technology Co.,Ltd.**

Factory Address: **NO.29 South Road, Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, China**

Brands: **Jixiang**

Products:

1. Disposable PVC Gloves
2. Disposable Nitrile Gloves

MEMBER OF International Halal Integrity ALLIANCE 國際清真誠信聯盟成員

Mohammad Zubair

Hafiz Mohammad Zubair
Director & Chief Executive Officer

28 Dec, 2020 to 28 Dec, 2023
Validity Period

EC Declaration of Conformity

Manufacturer:

Fujian Jixiang Medical Technology Co. , Ltd.
29 Ting Zhou Avenue South Road, Cewu Town,
Chang Ting County, FuJian Province
HongSong Xu
Tel: + 86-0597-6856569
E-mail: 627913027@qq.com

whose single Authorized EU-Representative:

M/S CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100

We, the manufacturer, herewith declare that the products

Disposable PVC Gloves
PVC001

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

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

Fujian Jixiang Medical Technology Co., Ltd.
29 Ting Zhou Avenue South Road, Cewu Town, Chang Ting County, FuJian Province

2020.11.19
Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Fujian Jixiang Medical Technology Co. , Ltd.
29 Ting Zhou Avenue South Road, Cewu Town,
Chang Ting County, FuJian Province
HongSong Xu
Tel: + 86-0597-6856569
E-mail: 627913027@qq.com

whose single Authorized EU-Representative:

M/S CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100

We, the manufacturer, herewith declare that the products

Latex Gloves
RL001

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

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

Fujian Jixiang Medical Technology Co., Ltd.
29 Ting Zhou Avenue South Road, Cewu Town, Chang Ting County, FuJian Province

2020.11.19
Place, date

Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Fujian Jixiang Medical Technology Co. , Ltd.
29 Ting Zhou Avenue South Road, Cewu Town,
Chang Ting County, FuJian Province
HongSong Xu
Tel: + 86-0597-6856569
E-mail: 627913027@qq.com

whose single Authorized EU-Representative:

M/S CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006, Málaga-Spain
Tel: +34951214054
Fax: +34952330100

We, the manufacturer, herewith declare that the products

Nitrile Gloves
DJ001

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

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

Fujian Jixiang Medical Technology Co., Ltd.
29 Ting Zhou Avenue South Road, Cewu Town, Chang Ting County, FuJian Province

2020.11.19
Place, date

Legally binding signature, Function

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/30112020.10

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Fujian Jixiang Medical Technology Co. , Ltd
29 Ting Zhou Avenue South Road, Cewu Town,
Chang Ting County, Fujian Province

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/2755/2020**

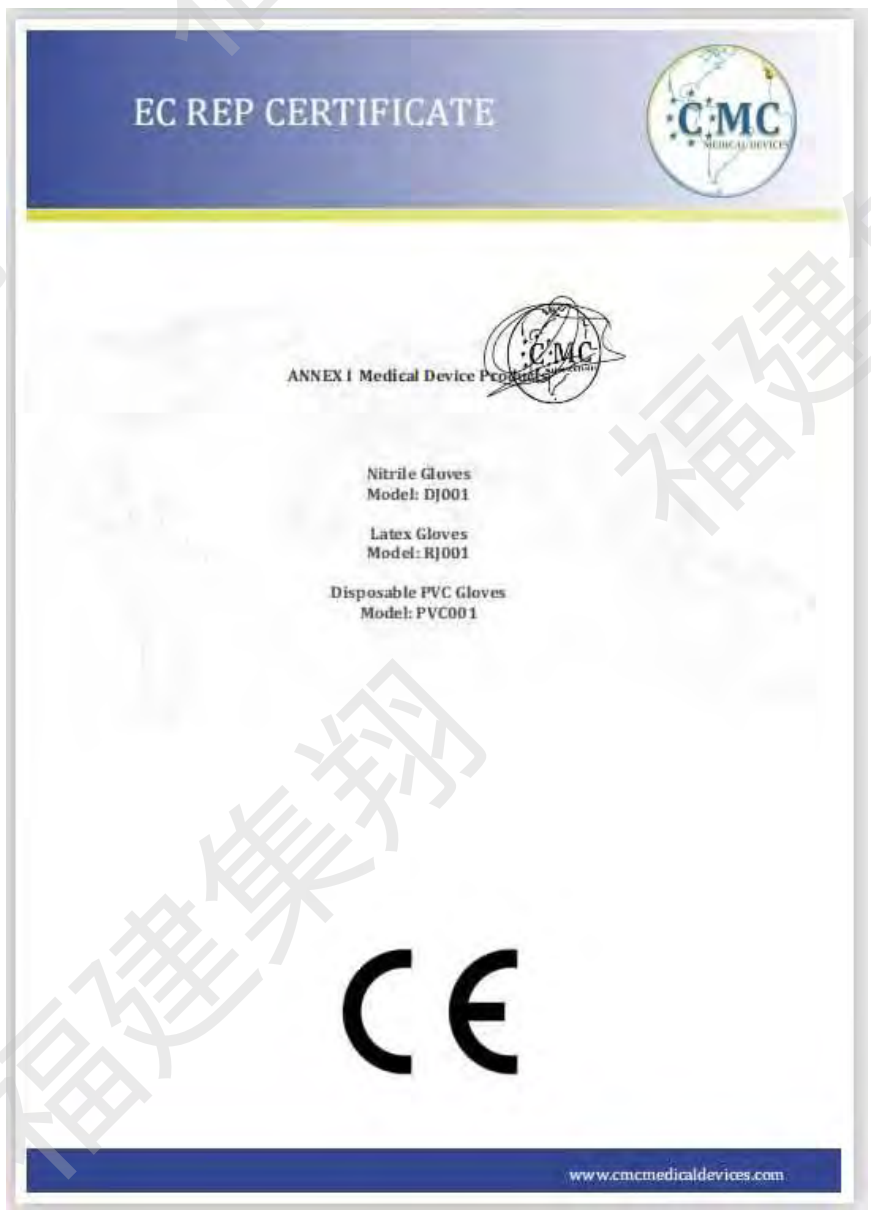
CE

Issued on: 30/11/2020

Valid until: 29/11/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

www.cmcmedicaldevices.com



EC REP CERTIFICATE

ANNEX I Medical Device Product Scope

Nitrile Gloves
Model: DJ001

Latex Gloves
Model: RJ001

Disposable PVC Gloves
Model: PVC001

CE

www.cmcmedicaldevices.com

THANKS!!!