编 号 320281666202102050195

统一社会信用代码

91320281MA256Q8777 （1/1）

营业执照

（副 本）

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称　江苏茂林医疗科技有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　韦淞耀

经营范围　许可项目：医护人员防护用品生产（Ⅱ类医疗器械）；卫生用品和一次性使用医疗用品生产；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；医用口罩生产；货物进出口；技术进出口；进出口代理（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，具体经营项目以审批结果为准）
一般项目：工程和技术研究和试验发展；医护人员防护用品生产（Ⅰ类医疗器械）；医护人员防护用品批发；医护人员防护用品零售；卫生用品和一次性使用医疗用品销售；橡胶制品制造；橡胶制品销售；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；医用口罩批发；医用口罩零售；日用口罩（非医用）生产；日用口罩（非医用）销售；劳动保护用品生产；劳动保护用品销售；特种劳动防护用品生产；特种劳动防护用品销售；消毒剂销售（不含危险化学品）；服装制造；服饰制造；服装服饰批发；纺织、服装及家庭用品批发；服装辅料销售；产业用纺织制成品生产；产业用纺织制成品销售；家用纺织制成品制造；塑料制品制造；塑料制品销售；针纺织品及原料销售（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）

注册资本　1000万元整

成立日期　2021年02月05日

营业期限　2021年02月05日至2051年02月04日

住　　所　江阴市月城镇月翔路29号

登记机关　江阴市行政审批局

2021 年 02 月 05 日

对外贸易经营者备案登记表

统一社会信用代码：91320281MA256Q8777

备案登记表编号：03335897　　进出口企业代码：----------

经营者中文名称	江苏茂林医疗科技有限公司		
经营者英文名称	Jiangsu Maolin 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	江阴市月城镇月翔路29号		
经营场所（中文）	江阴市月城镇月翔路29号		
经营场所（英文）	No.29,Yuexiang Road,Yuecheng Town,Jiangyin City.		
联系电话	0510-86583186	联系传真	0510-86583286
邮政编码	214404	电子邮箱	779374208@qq.com
工商登记注册日期	2021-2-5	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	韦淞耀	有效证件号	450422198809143031
注册资金	壹仟万元		（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	

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

2021 年 03 月 02 日

171020340088

检测报告

报告编号	HAPFD21030204	第 1 页	共 3 页
申请公司	江苏茂林医疗科技有限公司		
地　　址	中国江苏江阴市月城镇月翔路 29 号		
生产单位	江苏茂林医疗科技有限公司		
地　　址	中国江苏江阴市月城镇月翔路 29 号		
样品信息			
样品名称	一次性丁腈手套	样品品牌	——
生产日期或批号	——	规格型号	——
样品数量	——	样品来源/状态	送样/符合检验要求
*以上信息内容由申请人提供并确认			
接样日期	2021-03-08		
检测日期	2021-03-08—2021-03-12		
检测要求	根据客户要求，依据 GB 4806.11-2016 对样品测定以下项目：感官要求、高锰酸钾消耗量、重金属（以 Pb 计）、总迁移量。		
检测结果	见后续页		

编　　制：_____　　审　　核：_____

签　　发：_____　　签发日期：2021-03-12
授权签字人

验证报告网址：认监委验证平台 yz. cnca. cn

检测报告

检测结论 样品经检验，所测项目符合 GB 4806.11-2016 产品标准的规定要求，检验合格。判定如下：

序号	检测项目		要求	检测方法	结果	单项判定
1	感官要求		色泽正常、无异臭，污物	GB 4806.11-2016	符合	符合
			迁移试验所得浸泡液不应有着色，浑浊，沉淀异臭等感官性的劣变		符合	
2	高锰酸钾消耗量（mg/kg）		≤10	GB 31604.2-2016	1.6	符合
3	重金属（以 Pb 计）（mg/kg）		≤1	GB 31604.9-2016 第一法	＜0.1	符合
4	总迁移量（mg/dm^2）	水	≤10	GB 31604.8-2016	＜1	符合

备注：（1）1mg/kg=1ppm=0.0001%

（2）高锰酸钾消耗量试验条件：水，60℃，0.5h

（3）重金属（以 Pb 计）试验条件：4%乙酸，60℃，0.5h

（4）总迁移量试验条件：水，40℃，0.5h

样品照片：

报告结束

检测报告

注 意 事 项

Notice Items

1、本报告无批准人签字、报告专用章及骑缝章无效。
This report shall be invalid without the signature of the approver, the special seal for the report and the cross-page seal.

2、本报告不得擅自修改、增加或删除。
This report shall not be modified, added or deleted without authorization.

3、报告结果只对本次受检样品负责。若对检测结果有异议，请在报告签发日期后十五天内书面提出，逾期不予受理。
The results of the report are only responsible for the samples tested this time. If there is any objection to the test result, please submit it in writing within fifteen days after the date of issuance of the report. Overdue will not be accepted.

4、未经环谱检测书面同意，不得部分复制本报告，亦不可作为宣传品使用。
Without the written consent of HAP, this report shall not be partially copied or used as publicity materials.

5、当需要结果符合性评价时，若客户无要求，一般不考虑结果的测量不确定度的影响。
When the result conformity evaluation is required, if the customer does not require it, the influence of the measurement uncertainty of the result is generally not considered.

6、相关项目（△）未取得资质认定时，检测数据仅限科研、教学、内部质量控制或研发等活动使用。
When the relevant Items (△) has not been qualified, the test data is limited to scientific research, teaching, internal quality control or research and development activities.

7、本公司出具纸质正版报告与电子数字签名版具备相同效力，当两者内容有差异时以电子数字签名版为准。
The company's paper genuine report has the same legal effect as the electronic digital signature version. When the contents are different, subject to electronic digital signature version.

（具体通用条款详见 http://www.hap-test.com/company/tytk）
(For specific general terms, please see http://www.hap-test.com/company/tytk)

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天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.

国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

TTTS-WF21001008

检验检测报告
Test Report

客户提供信息及要求	委托单位/地址	江苏茂林医疗科技有限公司	送样人： /	
		中国江苏江阴市月城镇月翔路29号	电话： /	
	生产单位/地址	/		
		/		
	样品信息	样品名称： 一次性医用丁腈检查手套（非无菌）	商标： /	
		样品总数： 100只		
		号型规格： /	颜色： /	
		质量等级： /	安全类别： /	
		产品款号或货号： /		
	判定标准： /			
样品描述	1# 蓝色手套			
检验性质	委托检验	样品接收日期	2021-03-08	报告发布日期 2021-03-11
检验日期	2021-03-08 至 2021-03-11			
执行标准	见附页			
检验结论	检验结果见附页。 检验单位盖章			
备注	/			

批准： 审核： 编制：

检测项目	项目描述	单位	标准值	实测值	评价	执行标准/备注
1# 蓝色手套						
不透水试验	/	/	/	不渗漏	/	GB 10213-2006
尺寸	宽度	mm	/	92	/	GB 10213-2006
	最小长度	mm	/	237		
	最小厚度（大约在手掌中心）光面区域	mm	/	0.09		
	最小厚度（距中指指端13mm±3mm）麻面区域	mm	/	0.13		
	最大厚度（大约在手掌中心）光面区域	mm	/	0.09		
拉伸性能	老化前扯断力的最小值	N	/	10.4	/	ISO 37:2017
	老化前扯断伸长率的最小值	%	/	889		

天纺标检测认证股份有限公司
TianFangBiao Standardization Certification & Testing Co.,Ltd.
国家服装质量监督检验中心（天津）
National Clothing Quality Inspection & Supervision Center(Tianjin)
国家针织产品质量监督检验中心
National Knitted Product Quality Inspection & Supervision Center

检验检测报告
Test Report

样　品

JIANGSU MAOLIN MEDICAL TECHNOLOGY CO., LTD
29 YUEXIANG ROAD,YUECHENG TOWN,JIANGYIN CITY,JIANGSU PROVINCE,China

Sample Description : DISPOSABLE POWDER FREE 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. : XMNHG2100263701

Sample Receiving Date : Mar 08, 2021

Test Performing Date : Mar 08, 2021 to Mar 15, 2021

Test Performed : Selected test(s) as requested by applicant

Test Result(s) : For further details, please refer to the following page(s)

Test Requested : As requested by client, SVHC screening is performed according to:

(i) Two hundred and eleven (211) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 19, 2021 regarding Regulation (EC) No 1907/2006 concerning the REACH.

Summary :

According to the specified scope and evaluation screening, the test results of SVHC are ≤ 0.1% (w/w) in the submitted sample. PASS

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

scan to see the report

XMHL2103001030OT

Beck Hong
Authorized Signatory

Remark :

1. The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA: http://echa.europa.eu/web/guest/candidate-list-table
These lists are under evaluation by ECHA and may subject to change in the future.
2. REACH obligation:
2.1 Concerning article(s):
Communication:
Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.

Notification:
In accordance with Regulation (EC) No 1907/2006, any EU producer or importer of articles shall notify ECHA, in accordance with paragraph 4 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation, if (a) the substance in the Candidate List is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance in the Candidate List is present in those articles above a concentration of 0.1% weight by weight (w/w).

SGS adopts the ruling of the Court of Justice of the European Union on the definition of an article under REACH unless indicated otherwise. Detail explanation is available at the following link:
http://www.sgs.com/-/media/global/documents/technical-documents/technical-bulletins/sgs-crs-position-statement-on-svhc-in-articles-a4-en-16-06.pdf?la=en

2.2 Concerning material(s):
Test results in this report are based on the tested sample. This report refers to testing result of tested sample submitted as homogenous material(s). In case such material is being used to compose an article, the results indicated in this report may not represent SVHC concentration in such article. If this report refers to testing result of composite material group by equal weight proportion, the material in each composite test group may come from more than one article.

If the sample is a substance or mixture, and it directly exports to EU, client has the obligation to comply with the supply chain communication obligation under Article 31 of Regulation (EC) No. 1907/2006 and the conditions of Authorization of substance of very high concern included in the Annex XIV of the Regulation (EC) No. 1907/2006.

2.3 Concerning substance and preparation:
If a SVHC is found over 0.1% (w/w) and/or the specific concentration limit which is set in

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中国·福建·厦门·火炬（翔安）产业区翔虹路31号 邮编: 361101 t (86-592) 5766537 f (86-592) 5766460 e sgs.china@sgs.com

Regulation (EC) No 1272/2008 and its amendments, client is suggested to prepare a Safety Data Sheet (SDS) against the SVHC to comply with the supply chain communication obligation under Regulation (EC) No 1907/2006, in which:
- a substance that is classified as hazardous under the CLP Regulation (EC) No 1272/2008.
- a mixture that is classified as hazardous under the CLP Regulation (EC) No 1272/2008, when it contains a substance with concentration equal to, or greater than the classification limit as set in Regulation (EC) No. 1272/2008; or
- a mixture is not classified as hazardous under the CLP Regulation (EC) No 1272/2008, but contains either:
(a) a substance posing human health or environmental hazards in an individual concentration of ≥ 1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or ≥ 0.2 % by volume for gaseous mixtures; or
(b) a substance that is PBT, or vPvB in an individual concentration of ≥ 0.1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures); or
(c) a substance on the SVHC candidate list (for reasons other than those listed above), in an individual concentration of ≥ 0.1 % by weight for non-gaseous mixtures; or
(d) a substance for which there are Europe-wide workplace exposure limits.

3. If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

Test Sample :

Sample Description :

Specimen No.	SGS Sample ID	Description
SN1	XMN21-002637.001	Blue rubber gloves

Test Method :
SGS In-House method- SGS-CCL-TOP-092-01, SGS-CCL-TOP-092-02, Analyzed by ICP-OES, UV-VIS, GC-MS, HPLC-DAD/MS and Colorimetric Method.

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Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Notes :

1.The table above only shows detected SVHC, and SVHC that below RL are not reported.
Please refer to Appendix for the full list of tested SVHC.
2.RL = Reporting Limit (Test data will be shown if it ≥ RL. RL is not regulatory limit.) ND = Not detected (lower than RL),
ND is denoted on the SVHC substance.
3.* The test result is based on the calculation of selected element(s) and to the worst-case scenario.
** The test result is based on the calculation of selected marker(s) and to the worst-case scenario.
For detail information, please refer to the SGS REACH website:
http://www.sgs.com/en/Consumer-Goods-Retail/Toys-and-Juvenile-Products/Toys/REACH/Management-of-SVHC.aspx
4. RL = 0.005% is evaluated for element (i.e. cobalt, arsenic, lead, chromium (VI), aluminum, zirconium, boron, strontium, zinc, antimony, cadmium, titanium and barium respectively), except molybdenum RL=0.0005%, boron RL=0.0025% (only for Lead bis(tetrafluoroborate)).
5. Calculated concentration of boric compounds are based on the water extractive boron by ICP-OES.
6. § The substance is proposed for the identification as SVHC only where it contains Michler's ketone (CAS Number: 90-94-8) or Michler's base (CAS Number: 101-61-1) ≥0.1% (w/w).
7.The test was subcontracted to SGS Guangzhou chemical lab.

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4' -Diaminodiphenylmethane(MDA)	101-77-9	0.050
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.050
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.050
I	4	Anthracene	120-12-7	0.050
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.050
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.050
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.050
I	8	Cobalt dichloride*	7646-79-9	0.005
I	9	Diarsenic pentaoxide*	1303-28-2	0.005
I	10	Diarsenic trioxide*	1327-53-3	0.005
I	11	Dibutyl phthalate (DBP)	84-74-2	0.050
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α-HBCDD, β-HBCDD, γ-HBCDD)	-	0.050
I	13	Lead hydrogen arsenate*	7784-40-9	0.005
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.005
I	15	Triethyl arsenate*	15606-95-8	0.005
II	16	2,4-Dinitrotoluene	121-14-2	0.050
II	17	Acrylamide	79-06-1	0.050
II	18	Anthracene oil**	90640-80-5	0.050
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.050
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.050

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
II	21	Anthracene oil, anthracene paste, distn. lights**	91995-17-4	0.050
II	22	Anthracene oil, anthracene-low**	90640-82-7	0.050
II	23	Diisobutyl phthalate	84-69-5	0.050
II	24	Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*	12656-85-8	0.005
II	25	Lead chromate*	7758-97-6	0.005
II	26	Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	0.005
II	27	Pitch, coal tar, high temp.**	65996-93-2	0.050
II	28	Tris(2-chloroethyl)phosphate	115-96-8	0.050
III	29	Ammonium dichromate*	7789-09-05	0.005
III	30	Boric acid*	-	0.005
III	31	Disodium tetraborate, anhydrous*	1303-96-4, 1330-43-4, 12179-04-3	0.005
III	32	Potassium chromate*	7789-00-6	0.005
III	33	Potassium dichromate*	7778-50-9	0.005
III	34	Sodium chromate*	7775-11-03	0.005
III	35	Tetraboron disodium heptaoxide, hydrate*	12267-73-1	0.005
III	36	Trichloroethylene	79-01-6	0.050
IV	37	2-Ethoxyethanol	110-80-5	0.050
IV	38	2-Methoxyethanol	109-86-4	0.050
IV	39	Chromic acid, Oligomers of chromic acid and dichromic acid, Dichromic acid*	-	0.005

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
IV	40	Chromium trioxide*	1333-82-0	0.005
IV	41	Cobalt(II) carbonate*	513-79-1	0.005
IV	42	Cobalt(II) diacetate*	71-48-7	0.005
IV	43	Cobalt(II) dinitrate*	10141-05-6	0.005
IV	44	Cobalt(II) sulphate*	10124-43-3	0.005
V	45	1,2,3-trichloropropane	96-18-4	0.050
V	46	1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	0.050
V	47	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	0.050
V	48	1-methyl-2-pyrrolidone	872-50-4	0.050
V	49	2-ethoxyethyl acetate	111-15-9	0.050
V	50	Hydrazine	7803-57-8, 302-01-2	0.050
V	51	Strontium chromate*	7789-06-02	0.005
VI	52	1,2-Dichloroethane	107-06-2	0.050
VI	53	2,2'-dichloro-4,4'-methylenedianiline	101-14-4	0.050
VI	54	2-Methoxyaniline; o-Anisidine	90-04-0	0.050
VI	55	4-(1,1,3,3-tetramethylbutyl)phenol	140-66-9	0.050
VI	56	Aluminosilicate Refractory Ceramic Fibres *	-	0.005
VI	57	Arsenic acid*	7778-39-4	0.005
VI	58	Bis(2-methoxyethyl) ether	111-96-6	0.050
VI	59	Bis(2-methoxyethyl) phthalate	117-82-8	0.050

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VI	60	Calcium arsenate*	7778-44-1	0.005
VI	61	Dichromium tris(chromate) *	24613-89-6	0.005
VI	62	Formaldehyde, oligomeric reaction products with aniline	25214-70-4	0.050
VI	63	Lead diazide, Lead azide*	13424-46-9	0.005
VI	64	Lead dipicrate*	6477-64-1	0.005
VI	65	Lead styphnate*	15245-44-0	0.005
VI	66	N,N-dimethylacetamide	127-19-5	0.050
VI	67	Pentazinc chromate octahydroxide*	49663-84-5	0.005
VI	68	Phenolphthalein	77-09-8	0.050
VI	69	Potassium hydroxyoctaoxodizincatedichromate*	11103-86-9	0.005
VI	70	Trilead diarsenate*	3687-31-8	0.005
VI	71	Zirconia Aluminosilicate Refractory Ceramic Fibres*	-	0.005
VII	72	[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)§	2580-56-5	0.050
VII	73	[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3)§	548-62-9	0.050
VII	74	1,2-bis(2-methoxyethoxy)ethane (TEGDME; triglyme)	112-49-2	0.050
VII	75	1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	0.050
VII	76	4,4'-bis(dimethylamino) benzophenone (Michler's Ketone)	90-94-8	0.050
VII	77	4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol§	561-41-1	0.050
VII	78	Diboron trioxide*	1303-86-2	0.005

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VII	79	Formamide	75-12-7	0.050
VII	80	Lead(II) bis(methanesulfonate)*	17570-76-2	0.005
VII	81	N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	0.050
VII	82	TGIC (1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione)	2451-62-9	0.050
VII	83	α,α-Bis[4-(dimethylamino)phenyl]-4 (phenylamino)naphthalene-1-methanol (C.I. Solvent Blue 4) §	6786-83-0	0.050
VII	84	β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	59653-74-6	0.050
VIII	85	[Phthalato(2-)]dioxotrilead*	69011-06-9	0.005
VIII	86	1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	0.050
VIII	87	1,2-Diethoxyethane	629-14-1	0.050
VIII	88	1-Bromopropane	106-94-5	0.050
VIII	89	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	0.050
VIII	90	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	0.050
VIII	91	4,4'-Methylenedi-o-toluidine	838-88-0	0.050
VIII	92	4,4'-Oxydianiline and its salts	101-80-4	0.050
VIII	93	4-Aminoazobenzene	60-09-3	0.050
VIII	94	4-Methyl-m-phenylenediamine	95-80-7	0.050
VIII	95	4-Nonylphenol, branched and linear	-	0.050
VIII	96	6-Methoxy-m-toluidine	120-71-8	0.050
VIII	97	Acetic acid, lead salt, basic*	51404-69-4	0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	98	Biphenyl-4-ylamine	92-67-1	0.050
VIII	99	Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	0.050
VIII	100	Cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride	-	0.050
VIII	101	Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	0.050
VIII	102	Dibutyltin dichloride (DBTC)	683-18-1	0.050
VIII	103	Diethyl sulphate	64-67-5	0.050
VIII	104	Diisopentylphthalate	605-50-5	0.050
VIII	105	Dimethyl sulphate	77-78-1	0.050
VIII	106	Dinoseb	88-85-7	0.050
VIII	107	Dioxobis(stearato)trilead*	12578-12-0	0.005
VIII	108	Fatty acids, C16-18, lead salts*	91031-62-8	0.005
VIII	109	Furan	110-00-9	0.050
VIII	110	Henicosafluoroundecanoic acid	2058-94-8	0.050
VIII	111	Heptacosafluorotetradecanoic acid	376-06-7	0.050
VIII	112	Hexahydromethylphathalic anhydride, Hexahydro-4-methylphathalic anhydride, Hexahydro-1-methylphathalic anhydride, Hexahydro-3-methylphathalic anhydride	-	0.050
VIII	113	Lead bis(tetrafluoroborate)*	13814-96-5	0.005
VIII	114	Lead cyanamidate*	20837-86-9	0.005
VIII	115	Lead dinitrate*	10099-74-8	0.005
VIII	116	Lead monoxide*	1317-36-8	0.005

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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	117	Lead oxide sulfate*	12036-76-9	0.005
VIII	118	Lead tetroxide (orange lead)*	1314-41-6	0.005
VIII	119	Lead titanium trioxide*	12060-00-3	0.005
VIII	120	Lead titanium zirconium oxide*	12626-81-2	0.005
VIII	121	Methoxyacetic acid	625-45-6	0.050
VIII	122	Methyloxirane (Propylene oxide)	75-56-9	0.050
VIII	123	N,N-dimethylformamide	68-12-2	0.050
VIII	124	N-Methylacetamide	79-16-3	0.050
VIII	125	N-Pentyl-isopentylphthalate	776297-69-9	0.050
VIII	126	o-Aminoazotoluene	97-56-3	0.050
VIII	127	o-Toluidine	95-53-4	0.050
VIII	128	Pentacosafluorotridecanoic acid	72629-94-8	0.050
VIII	129	Pentalead tetraoxide sulphate*	12065-90-6	0.005
VIII	130	Pyrochlore, antimony lead yellow*	8012-00-8	0.005
VIII	131	Silicic acid, barium salt, lead-doped*	68784-75-8	0.005
VIII	132	Silicic acid, lead salt*	11120-22-2	0.005
VIII	133	Sulfurous acid, lead salt, dibasic*	62229-08-7	0.005
VIII	134	Tetraethyllead*	78-00-2	0.005
VIII	135	Tetralead trioxide sulphate*	12202-17-4	0.005
VIII	136	Tricosafluorododecanoic acid	307-55-1	0.050
VIII	137	Trilead bis(carbonate)dihydroxide (basic lead carbonate)*	1319-46-6	0.005

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
VIII	138	Trilead dioxide phosphonate*	12141-20-7	0.005
IX	139	4-Nonylphenol, branched and linear, ethoxylated	-	0.050
IX	140	Ammonium pentadecafluorooctanoate (APFO)**	3825-26-1	0.050
IX	141	Cadmium oxide*	1306-19-0	0.005
IX	142	Cadmium*	7440-43-9	0.005
IX	143	Dipentyl phthalate (DPP)	131-18-0	0.050
IX	144	Pentadecafluorooctanoic acid (PFOA)	335-67-1	0.050
X	145	Cadmium sulphide*	1306-23-6	0.005
X	146	Dihexyl phthalate	84-75-3	0.050
X	147	Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	0.050
X	148	Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	0.050
X	149	Imidazolidine-2-thione; (2-imidazoline-2-thiol)	96-45-7	0.050
X	150	Lead di(acetate)*	301-04-2	0.005
X	151	Trixylyl phosphate	25155-23-1	0.050
XI	152	1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	0.050
XI	153	Cadmium chloride*	10108-64-2	0.005
XI	154	Sodium perborate; perboric acid, sodium salt*	-	0.005
XI	155	Sodium peroxometaborate*	7632-04-04	0.005

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XII	156	2-(2H-Benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	0.050
XII	157	2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	0.050
XII	158	2-Ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; DOTE	15571-58-1	0.050
XII	159	Cadmium fluoride*	7790-79-6	0.005
XII	160	Cadmium sulphate*	10124-36-4, 31119-53-6	0.005
XII	161	Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate & 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE & MOTE)	-	0.050
XIII	162	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate	-	0.050
XIII	163	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	0.050
XIV	164	1,3-propanesultone	1120-71-4	0.050
XIV	165	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	3864-99-1	0.050
XIV	166	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	36437-37-3	0.050
XIV	167	Nitrobenzene	98-95-3	0.050
XIV	168	Perfluorononan-1-oic-acid and its sodium and ammonium salts	-	0.050
XV	169	Benzo[def]chrysene (Benzo[a]pyrene)	50-32-8	0.050

Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XVI	170	4,4'-isopropylidenediphenol (bisphenol A)	80-05-7	0.050
XVI	171	4-Heptylphenol, branched and linear	-	0.050
XVI	172	Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts	-	0.050
XVI	173	p-(1,1-dimethylpropyl)phenol	80-46-6	0.050
XVII	174	Perfluorohexane-1-sulphonic acid and its salts	-	0.050
XVIII	175	1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™) [covering any of its individual anti- and syn-isomers or any combination thereof]	-	0.050
XVIII	176	Benz[a]anthracene	56-55-3	0.050
XVIII	177	Cadmium nitrate*	10325-94-7	0.005
XVIII	178	Cadmium carbonate*	513-78-0	0.005
XVIII	179	Cadmium hydroxide*	21041-95-2	0.005
XVIII	180	Chrysene	218-01-9	0.050
XVIII	181	Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) [with ≥0.1% w/w 4-heptylphenol, branched and linear]	-	0.050
XIX	182	Benzene-1,2,4-tricarboxylic acid 1,2-anhydride (trimellitic anhydride)	552-30-7	0.050
XIX	183	Benzo[ghi]perylene	191-24-2	0.050
XIX	184	Decamethylcyclopentasiloxane (D5)	541-02-6	0.050
XIX	185	Dicyclohexyl phthalate (DCHP)	84-61-7	0.050
XIX	186	Disodium octaborate*	12008-41-2	0.005
XIX	187	Dodecamethylcyclohexasiloxane (D6)	540-97-6	0.050

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XIX	188	Ethylenediamine	107-15-3	0.050
XIX	189	Lead*	7439-92-1	0.005
XIX	190	Octamethylcyclotetrasiloxane (D4)	556-67-2	0.050
XIX	191	Terphenyl hydrogenated	61788-32-7	0.050
XX	192	1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor)	15087-24-8	0.050
XX	193	2,2-bis(4'-hydroxyphenyl)-4- methylpentane	6807-17-6	0.050
XX	194	Benzo[k]fluoranthene	207-08-9	0.050
XX	195	Fluoranthene	206-44-0	0.050
XX	196	Phenanthrene	85-01-8	0.050
XX	197	Pyrene	129-00-0	0.050
XXI	198	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	-	0.050
XXI	199	2-methoxyethyl acetate	110-49-6	0.050
XXI	200	4-tert-butylphenol (PTBP)	98-54-4	0.050
XXI	201	Tris(4-nonylphenyl,branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)	-	0.050
XXII	202	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	0.050
XXII	203	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5	0.050
XXII	204	Diisohexyl phthalate	71850-09-4	0.050
XXII	205	Perfluorobutane sulfonic acid (PFBS) and its salts	-	0.050

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Appendix
Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
XXIII	206	1-vinylimidazole	1072-63-5	0.050
XXIII	207	2-methylimidazole	693-98-1	0.050
XXIII	208	Butyl 4-hydroxybenzoate	94-26-8	0.050
XXIII	209	Dibutylbis(pentane-2,4-dionato-O,O')tin**	22673-19-4	0.050
XXIV	210	bis(2-(2-methoxyethoxy)ethyl) ether	143-24-8	0.050
XXIV	211	Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety**	-	0.050

Sample photo(s):

XMNHG2100263701

XMN21-002637.001

End of Report

SGS-CSTC Standards Technical Services Co., Ltd. Xiamen Branch Testing Center Hardlines
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SUBJECT	**Chemical Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	**Jiangsu Maolin Medical Technology Co., Ltd**
CLIENT ADDRESS	29 Yuexiang Road, Yuecheng Town, Jiangyin City, Jiangsu Province, China
TEST PERIOD	05-Mar-2021~12-Mar-2021
RESULT SUMMARY	The tested items **complied with** US FDA 21 CFR 177.2600 Rubber articles intended for repeated use - Distilled Water extractives **PASS** - n-Heptane extractives **PASS**

Prepared By

Cynthia Cao

(Cynthia Cao)
Report Drafter

Authorized By

Leo Li

(Leo Li)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
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Regional Head Office:
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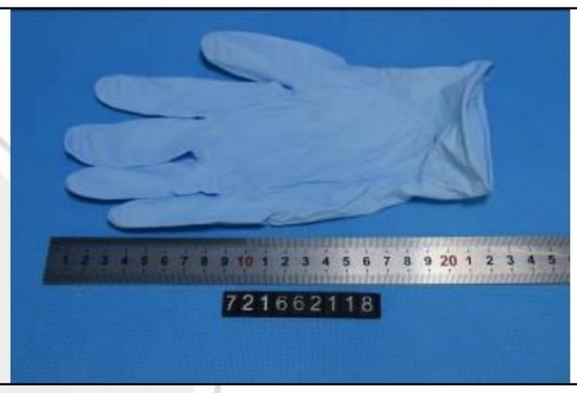
No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE / TEST DATE

05-Mar-2021/ 05-Mar-2021

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED BY/ ON BEHALF OF THE CLIENTS AS

Sample Name: Disposable Powder Free Nitrile Gloves
Sample Specification: /
Batch No./Date: /
Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721662118	Blue glove	

TEST RESULT(S)

1. Test for compliance with US FDA 21 CFR 177.2600
- Test method: With reference to US FDA 21 CFR 177.2600

Test Item		Result [mg/in²]	FDA Specification [mg/in²]
Distilled Water extractives at reflux temperature	First 7 hours	2.74	20
	Succeeding 2 hours	0.200	1
n-Hexane extractives at reflux temperature	First 7 hours	0.716	175
	Succeeding 2 hours	0.158	4

Note: This report is for internal use only such as internal scientific research, education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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Regional Head Office:
TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report No. 7191255829-EEC21-WBH
dated 09 Apr 2021

PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by Jiangsu Maolin Medical Technology Co., Ltd. on 10 Mar 2021.

TESTED FOR:

Jiangsu Maolin Medical Technology Co., Ltd.
29 Yuexiang Road, Yuecheng Town,
Jiangyin City, Jiangsu Province,
China

TEST DATE:

11 Mar 2021 to 06 Apr 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Expiry Date	Size	Sample Received (pieces)	Manufacturer
1	Disposable Medical Nitrile Examination Gloves (non-sterile)	Moaln/ ML-001	Blue	CH20210201	2024-02	M	300	Jiangsu Maolin Medical Technology Co., Ltd.

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

METHOD OF TEST:

1. EN 455-1:2020 Medical gloves for single use
   Part 1: Requirements and testing for freedom from holes

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

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
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TÜV SÜD Asia Pacific Pte. Ltd.
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TÜV®

RESULTS:

Sample: Disposable Medical Nitrile Examination Gloves (non-sterile), Moaln/ ML-001, Blue, Size M

Table 1: Results for EN 455-1:2020

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	≥ 240	13	250	Passed
	b) Width (mm)	For Size M: 95 ± 10	13	96	Passed
5	Strength a) Force at break (N)	For nitrile examination gloves: ≥ 6.0	13	7.4	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	For nitrile examination gloves: ≥ 6.0	13	8.0	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Comply	Passed

RESULTS (cont'd):

Sample: Disposable Medical Nitrile Examination Gloves (non-sterile), Moaln/ ML-001, Blue, Size M

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is not dressed with talcum powder, based on client's declaration letter	Passed
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.68 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Not natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
			Inferred results: Passed

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REMARKS:

1. Labelling requirements are assessed based on the submitted packaging artwork by client.
2. NA: Not applicable for the submitted sample.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo 1: Disposable Medical Nitrile Examination Gloves (non-sterile), Moaln/ ML-001, Blue, Size M

Photo 2: Packaging artwork for Disposable Medical Nitrile Examination Gloves (non-sterile), Moaln/ ML-001, Blue, Size M

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 26 January 2021

Declaration of Conformity

Manufacturer: **Jiangsu Maolin Medical Technology Co., Ltd**

29 Yuexiang Road, Yuecheng Town, Jiangyin City, Jiangsu Province, China 214404

Authorized EU-Representative:

MB Global Service AB

Prastgatan 68, 111 29 Stockholm, Sweden

Email: Info@mbgls.com

We, the manufacturer, hereby declare the products listed below,

Disposable Medical Examination Gloves (Non-Sterile) GMDN Code 56286

Meet the provision of Directive 2017/745 which apply to them. The number of relevant technical document is CE-ML-N01.

The medical device has been classified as Class I medical device according to Rule I of Annex VIII of the Directive 2017/745.

The statement of this declaration of conformity is issued under the sole responsibility of the manufacturer. All non-sterile gloves supplied by the manufacturer are covered by the declaration.

According to the procedure relating to the EC Declaration of Conformity setting out in Annex IV of Directive 2017/745.

List of Harmonised standards,

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

EN455-2:2015 Medical gloves for single use. Requirements and testing for physical properties

EN455-3: 2015 Medical gloves for single use. Requirements and testing for biological evaluation

EN455-4:2009 Requirements and testing for shelf life determination

EN 980:2008 Symbols for use in the labelling of medical devices

Signature: Mao Yuan

Name (PRINTING): Mao Yuan Position: Manager of Regulatory Affairs

Issuing Date: March 25th, 2021 Issuing at: Jiangsu, China

Jiangsu Maolin Medical Technology Co., Ltd

Add: Prastgatan 68, 111 29 Stockholm, Sweden
PH: +46 709 988 357 Email: Info@mbgls.com

European Authorized Representative

Service Contract

This European Authorized Representative Service Contract (hereinafter referred to as "Contract") is made as of 25th March 2021 between **MB Global Service AB**, *located at Prastgatan 68, 111 29 Stockholm, Sweden (hereinafter referred to as "EAR"), and Jiangsu* **Maolin Medical Technology Co., Ltd.**, *located at 29 Yuexiang Road, Yuecheng Town, Jiangyin City, Jiangsu Province, China (hereinafter referred to as "Manufacturer").*

The EAR and the Manufacturer have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by the Manufacturer and sold to EU in order to comply to the requirements set out in the Regulation (EU) 2017/745 for Medical device or Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

1. Appointment:

1.1. The Manufacturer hereby appoints the EAR, who accepts such appointment, as their representative for the Products set out in Appendix A.

1.2. The responsibility of both parties is as stated hereafter.

1.3. The Service of the EAR covers the new Regulations for medical devices (EU) 2017/745 and in vitro diagnostic devices (EU) 2017/746.

2. Claim Handling

2.1. The EAR shall notify the Manufacturer about any received claims and any change of laws and regulations related to the Manufacturer's products set out in Appendix A.

2.2. The Manufacturer is the immediate responsible person for the claim handling and regulation compliance.

3. Incident Handling

3.1. On receiving information of an incident, as defined in the Regulation (EU) 2017/745, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

3.1.1. The EAR shall notify occurrence of any incident(s) in the EU to the Manufacturer immediately upon receiving any notification of an incident(s).

3.1.2. Upon receiving information of any incident(s) the Manufacturer shall perform the necessary analysis of the situation immediately and send the incident report to the EAR according to the requirements of latest version of Guidelines on the "Medical Devices Vigilance System". In that way the EAR can submit the report to the relevant Competent Authority as defined in the timescale of the latest version of "Guidelines on a Medical Devices Vigilance System".

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3.1.3. If applicable, based on the report, the Manufacturer shall instruct the EAR of the necessary countermeasures to be taken. The EAR shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by the Manufacturer.

4. Responsibilities on Technical Documentation:

4.1. The Manufacturer shall establish necessary procedures to prepare, maintain and update Technical Documentation including the Declaration of Conformity for the Products set out in Appendix A to be able to comply with the MDR/IVDR requirements.

4.2. The Manufacturer shall transfer the agreed Technical Documentation and Declaration of Conformity to the EAR upon request. The Manufacturer shall have the responsibility to provide to the EAR any additional documentation as

required by the Competent Authority or Notified Body.

4.3. The EAR shall provide a copy of the Contract to the competent authority upon request.

5. Instructions for Use (If applicable)

5.1. The Manufacturer shall be responsible for the content of the instructions for use and/ or user's manuals (hereinafter "IFUs"), and shall ensure that the English language IFUs are available to the EAR. If required by the local Competent Authorities, the Manufacturer shall produce the German translation of the IFU at their own cost and responsibility.

5.2. The Manufacturer shall ensure that the required local language IFUs are provided to the customers.

6. Registration

6.1. The EAR shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

6.2. The Manufacturer shall have all data allowing for identification of concerned devices together with the label and the IFUs available to the EAR upon request by competent authority.

7. Tasks to be performed by the EAR:

7.1. Verify that the EU declaration of conformity and technical documentation have been drawn up and where applicable, that an appropriate conformity assessment procedure has been carried out by the Manufacturer.

7.2. Keep the technical documentation, the EU declaration of conformity and if applicable, a copy of any relevant certificate, including any amendments and supplements available for the competent authorities for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

7.3. Comply with the registration obligations laid down in Art. 31 of (EU) 2017/745 or Art. 28 of (EU) 2017/746 and verify that the Manufacturer has complied with the registration obligations laid down in Art. 27 and 29 (EU) 2017/745 or Art. 24 and 26 of (EU) 2017/746.

7.4. In response to a request from a competent authority, provide the competent authority with all the information and documentation necessary to demonstrate the

conformity of a device, in an official union language determined by the member state concerned.

7.5. Forward to the Manufacturer any request by a competent authority of the member state in which the EAR has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device.

7.6. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices.

7.7. Terminate the Contract if the Manufacturer acts contrary to its obligations under this regulation.

7.8. The EAR will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

8. Obligations of the Manufacturer:

8.1. Must comply with all the requirements specified in Art. 10 (EU) 2017/745 or Art. 10 (EU) 2017/746 regarding general obligations of manufacturers.

8.2. Shall procure and maintain at all times during the term of the Contract a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of the Contract.

8.3. The Contract will not be valid if the manufacturer does not meet this requirement.

9. Other Obligations of the EAR & the Manufacturer:

9.1. The EAR shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.

9.2. The EAR shall rescind his contract with the Manufacturer if the latter does not provide him with the access to the necessary information.

9.3. The Manufacturer shall keep the EAR informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs 10 to 12 hereunder shall be informed.

10. Safeguard Clause

10.1. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/ or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the EAR, they should immediately communicate such measures to the Manufacturer and advise the Manufacturer as to the implications of this decision.

10.2. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the Manufacturer or the EAR". If the relevant Competent Authority contacts

the EAR, they should immediately communicate such information to the Manufacturer and advise the Manufacturer as to the implications of this decision.

11. Vigilance

11.1. In case of an incident and if the relevant Competent Authority contacts the EAR, they should immediately communicate such information to the Manufacturer and advise the Manufacturer as to the implications of this decision.

11.2. The Manufacturer should ensure that the EAR is kept informed of incident reports and Field Safety Corrective Actions.

12. Serious adverse events during clinical investigation

12.1. According to Art. 80 of (EU) 2017/745 and Art. 76 of (EU) 2017/746, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".

12.2. The EAR should inform the Manufacturer of decisions of a Member State in respect of refusal or restriction of the placing of the devices specified in Appendix A in the market.

13. Territory

The following countries represent The EAR's Business Area: EUROPEAN COMMUNITY TERRITORY

14. Remuneration

14.1. The Manufacturer agrees to remunerate "EAR" an annual fee for the services provided and detailed within this Contract.

14.2. Both parties agree that the above-mentioned remuneration does not include fees and/or taxes imposed by some European Competent Authorities and said fees and/or taxes are the responsibility of the Manufacturer.

14.3. The EAR will charge additional fees in case of customer compliant and investigation. The fees will be charged based on the situation and as per the mutual understanding. Traveling will be as per actual expenses.

14.4. Both parties agree that the above-mentioned annual remuneration assumes that "EAR"" activities do not include a vigilance event as defined by (EU) 2017/745 and (EU) 2017/746, and further defined in the "Guidelines on a Medical Device Vigilance System" (MEDDEV 2.12-1).

14.5. The handling of a vigilance event that entail notification to an authority or the need of expert opinion being obtained must be pre-approved in writing from the Manufacturer to the EAR prior to the EAR engaging in such additional service. The EAR shall invoice such additional service to the Manufacturer on a separate basis at the rate of 250 € per hour, up to the maximum fee as pre- approved in writing to Regulatory Authority from the Manufacturer.

15. Validity of the Contract

Unless otherwise earlier terminated as herein provided, this Contract will have a term of five (5) years, commencing from the date of this Contract as contained in the first paragraph of

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this Contract. The Contract will extend automatically for another year unless one of the parties cancels it by ninety (90) day's prior to written notice.

16. Place of Fulfilment, Domicile, Jurisdiction

Place of fulfilment and domicile is the domicile of "EAR". This Contract shall be governed by the substantive laws of the Kingdom of Sweden and is subject to the exclusive jurisdiction of the Kingdom of Sweden.

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Appendix A)

Medical Device Information

Sr. No.	*Device Name*	*Class & Rule*	*Technical File ID with issue date*
1	*Nitrile Disposable Medical Examination Gloves (Non-Sterile)*	*Class I, Rule 1*	*CE-ML-N001 25.03.2021*

The devices listed in the Declaration of Conformity are those devices that the EAR is responsible for, both in accordance with the Regulation (EU) 2017/745 and/or (EU) 2017/746 and with this Contract.

Attention is drawn to as per Art. 4 of this Contract, in which the Manufacturer agrees to update this Appendix and the respective DOCs every time an additional device is added to the European device program and to ensure that these devices are included in the Manufacturer's device liability insurance issued to the EAR.

For Manufacture

Authorized Signatory

Name: Mao Yuan

Designation: Manager of Regulatory Affairs

Date: 25.03.2021

For the EAR

MB GLOBAL SERVICE AB
REG # 559308 - 0145

Authorized Signatory

Name: Clara Holmstrom

Designation: General Manager

Date: 25.03.2021

Add: Prastgatan 68, 111 29 Stockholm, Sweden
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Appendix B)

Annual Service Fee

The Manufacturer agrees to remunerate "EAR" the amount of Two Thousand and Three Hundred Euros (€ 2300) per annum for the services provided and detailed within this Contract.

This amount is subject to be changed under the EAR's authority with a notice to the Manufacturer in one month advance.

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

Customer details: Jiangsu Maolin Medical Technology Co., Ltd.
Yuexiang Road
Yuecheng Town
Jiangyin City
Jiangsu Province
China

SATRA reference: CHT0309904 /2110

Your reference: ML-001

Date of report: 26 March 2021

Samples received: 10 March 2021

Date(s) work carried out: 15-22 March 2021

TECHNICAL REPORT

Subject: EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Powder Free Nitrile Gloves, Size: S6, M7, L8, XL9, Color: Blue, Reference number: ML-001

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: Adam Zhang
Position: Technologist
Department: China Testing

Adam Zhang

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Powder Free Nitrile Gloves, Size: S6, M7, L8, XL9, Color: Blue, Reference number: ML-001 were received by SATRA on 10 March 2021 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Samples described as Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: ML-001

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 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

CONCLUSION

The samples described as Disposable Powder Free Nitrile Gloves, Size: S6, M7, L8, XL9, Color: Blue, Reference number: ML-001 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 374-5: 2016 Clause 5.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value and DMFa

Detailed results are included on the following page(s)

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 6: 230 / 231 / 235 — Comfortable on fit 7: 237 / 239 / 231 — Comfortable on fit 8: 234 / 228 / 231 — Comfortable on fit 9: 236 / 235 / 235 — Comfortable on fit	± 1.10 mm	N/A
5.2 Dexterity	See table 1	Size / Minimum pin diameter / mm 6: 5.0 7: 5.0 8: 5.0 9: 5.0	N/A	Level 5

Signed: Adam Zhang
Technologist
China Testing

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

TECHNICAL REPORT

Protection Against Viruses Test Results

Testing was conducted at a third-party laboratory and reported under their reference 21R000813. The laboratory is CNAS accredited to ISO 17025: 2017 with ISO 16604: 2004 included in their accreditation schedule.

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

Sample description:	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: ML-001					
Test method	**Specimen**	**Step 1 (0 kPa, 5 min)**	**Step 2 (14 kPa, 1min)**	**Step 3 (0kPa, 4min)**	**Titre of phage Phi-X174 (PFU /mL)**	**Comment**
ISO 16604: 2004 Procedure B Using retaining screen	+ control	Penetration	Penetration	Penetration	Penetration	Acceptable
	- control	No penetration	No penetration	No penetration	< 1	Acceptable
	1	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	2	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass
	3	Invisible penetrate	Invisible penetrate	Invisible penetrate	< 1	Pass

TECHNICAL REPORT

Innocuousness Test Results

Testing was conducted at a third-party laboratory and reported under their reference A210313009001. The laboratory is CNAS accredited to ISO 17025: 2017.

Sample Item	Sample Description	Location	Style
I001	Disposable Powder Free Nitrile Gloves, Color: Blue, Reference number: ML-001	Gloves	-

pH Value - EN ISO 21420:2020

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

Requirement:	**3.5-9.5**

-	Unit	Result
Test Item(s)	-	**I001**
Test Method	-	**II**
Parameter	-	-
pH Value of Extracting Solution	-	5.46
Temp. of Aqueous Extract	deg. C	25.1
pH Value of Aqueous Extract	-	7.4
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.

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 hyrdocarbons 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

Dimethylformamide(DMFA) Content - EN ISO 21420:2020

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

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

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

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

Signed: Adam Zhang
Technologist
China Testing

TECHNICAL REPORT

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

1. GENERAL

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

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

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

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

1.5 All references in these terms and conditions to:

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

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

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

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

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

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

2 FEES AND PAYMENT

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

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

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

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

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

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

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

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

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

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

3 INTELLECTUAL PROPERTY RIGHTS

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

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

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

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

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

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

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

4 SUSPENSION OR TERMINATION OF SERVICES

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

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

5 LIABILITY AND INDEMNIFICATION

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

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

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

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

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

6 MISCELLANEOUS

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

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

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

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

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

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

7 CONFIDENTIALITY

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

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

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

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

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

8 AMENDMENT

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

9 DISPUTE RESOLUTION

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

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

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

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

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

10 PROVISION OF SERVICES

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

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

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

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

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

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

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

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

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

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

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

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

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

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

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

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

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

12 DELIVERY AND NON-DELIVERY OF GOODS

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

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

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

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

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

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

13 RISK/TITLE OF GOODS

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

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

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

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

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

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

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

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

13.4.1 hold the Goods as SATRA's bailee;

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

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

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

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

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

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

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

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

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

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

14 PATENTS

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

15 WARRANTY OF GOODS

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

16 DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Terms and conditions – May 2017