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## 源引力检测认证有限公司温州分公司

Source gravity detection certification co. LTD Wenzhou branch

# 认证协议书

Cert Agreement

甲方(委托方)/ Party A .: 浙江仁川医疗器械有限公司

项目名称/ Project Name.:

乙方(服务方) /Party B .: 源引力检测认证有限公司温州分公司

签订地点/ place.: ☐SQP 办公室 ☐客户办公室 ☒其它: E-mail

签订日期/Signing Date.: 2020-05-11

依据《中华人民共和国合同法》，甲乙双方就技术服务项目协商一致，签订本协议。

According to the Contract Law of the People's Republic of China, Party A and Party B have agreed to sign this agreement on this certification technique consultant item.

**1、服务项目及收费标准**（在□内划√表示适用于该项目）/ Service project of technique consultant  
(mark √ in □, it means it is appropriate to this project.)

选择 Choose	申请项目 project list	收费标准 Cost	机构 org	价格 Price
<input type="checkbox"/>	GB 2626-2006 检测报告 EAC certification (Russia)	根据际测试项目收费；	/	
<input checked="" type="checkbox"/>	 CE 认证（欧盟） EU CE Certification	9.8 万	TUV	
<input type="checkbox"/>	 SQP 2001 SQP2001-2019 阳光质造 现场 规范化管理体系 SQP2001-2019 Certification	5 万；（含 500 平方规划，超出按 15 元/平方收费）	SQP	
<input type="checkbox"/>	 FDA 认证 510K（美国） Food and Drug Administration		FDA	
<input checked="" type="checkbox"/>	 REACH (SVCH) 检测（欧盟） REACH (SVCH) Detection	1.5 万；	Tuv 或 SGS	
<input checked="" type="checkbox"/>	 EAC 认证（俄罗斯） EAC certification (Russia)	4.9（平面口罩豁免函）	EAC	
<input type="checkbox"/>	 EUA 认证（美国） EUA and Drug Administration	4.7 万	FDA	
<input type="checkbox"/>	 ROHS 环保检测（欧盟） ROHS Certification	0.8 万；	Tuv 或 SGS	
<input checked="" type="checkbox"/>	 ISO9001 国际质量管理体系 ISO9001 Quality Certification	1.2 万 (1-65 人)	CCCI	

## CE 特别说明:

序号	项目	内容	备注
1	FDA 注册	510K 豁免	官费 5236USD (企业自行支付)
2	现场规划	车间平面布局 图见附件	规划所需材料企业负责, 我公司人员差旅、食宿企业负责
	口罩 EN 检测	EN 标准实测	重测费用企业负责
	CE 公告号机构	B+C2 2 证	
	CE 质控体系		按 EN149 测试, 若不通过仅收测试费, 退还证书费

## 2、项目执行时间 / Project implementation date.

双方约定项目执行时间在 2020 年 5 月 25 日 至 2020 年 7 月 24 日 (如因甲方的原因致使项目周期拖延的, 乙方不承担相应责任)。

Both parties appointed the project implementation date from XXX to XXX(if because of Party A, the project period is delayed. Party B will not take the relevant responsibility.

## 3、项目收费 / Project fees

### 3.2 项目总费用 / The total cost of the project

类别	总金额 (小写)	总金额 (大写)	备注
首次服务	16.8 万	拾陆万捌万元	
持续维护			
再次服务			

☐ 不含发票/Non-tax invoices ☒ 含发票/Containing Tax Invoice

### 3.2 公司帐户 / Company Bank Account

名称：源引力检测认证有限公司

帐号：33050169460000000219

开户行：中国建设银行股份有限公司丽水开发区支行

### 3.3 费用支付方式及时间 / The methods and time of payment

#### 3.3.1 支付方式

甲方支付给乙方或乙方允许的第三方机构（需乙方提供支付第三方的说明函）所有费用公对公付款，并已含税，开具增值税普通发票。

Party A shall pay Party B or authorized third parties (with a covering letter provided by Party B) all the expenses by business-to-business payment, including tax, and issue ordinary VAT invoices.

#### 3.3.2 支付时间

签订协议后甲方在 3 天内支付 100%，如审核后不能发证的，将继续提供审核服务，直至通过为止或返还甲方所有款项。

Party A will pay 100% (for submitting the application) in 3 days when signing the agreement. If Party B can't issue the certification when examination and adoption, they will return back all the payment.

## 4、认证服务内容、形式和要求 / The content, type and requirement of certification technique

4.1 乙方负责制定总时间计划，督促双方按计划实施。

Party B takes charge of working out application certification date plan and supervising both parties to implement according to the plan.

4.2 为甲方主要管理人员进行有关标准及要求的贯彻、指导。

Party B provides the relevant implementation and training for main managerial personnel from Party A.

4.3 针对项目标准要求，对甲方进行技术性提供指导（必要时）。

To provide the technique guidance of design and development for Party A according to the project standard requirement (when necessary).

4.4 协助甲方为达到认证标准进行工厂硬件设施等改造提供必要的建议。

To assist Party A and provide the necessary guidance to meet certification standards for transformation of factory hardware facilities.

## 5、甲方的协作事项（需讲解） / Party A's cooperation items.

在协议生效后的一周内，甲方应向乙方提供下列主要配合事项：

Within one week after the agreement came into effect, Party A shall provide Party B with the following key issues:

5.1 指定一名负责人（管理者代表或项目代表）全过程配合乙方工作人员的工作。

Designate a responsible person (manager or project representative) to cooperate with technical advisory staff from Party B in the whole procedure.

5.2 明确技术服务项目计划。Clear technical advisory project plan.

5.3 为乙方提供中证技术服务所需的各项资源（如资料打印、复印设备等）。

To provide all resources which applying for certification technology advisory need for Party B (for example: printing document, copy equipment and so on).

5.4 按申证时间计划安排，做好工厂检查所需的各项记录等准备工作。

According to the arrangement of applying for certification plan, to do the preparatory job of making all the required records when factory inspection.

5.5 甲方必须妥善安排审核、指导老师差旅、食宿等事宜。

Party A must safely arrange the traveling, eating, dormitory and so on for the checking team teachers .

5.6 按《计量法》要求需送检的测量设备或必须进行型式检验的产品，必须及时送检，确保项目顺利完工（诸如此类的硬件费用甲方自行承担，也可委托乙方代办，费用实报实销）。【仅质量相关体系需要】

According to <Measurement Law>, if measurement equipment or products are required to be tested, must be sent in time to make sure the project can be finished successfully. (Such hardware fee is held by Party A).

## 6、风险告知 / Secretly promise

6.1、证书获得前的风险 / The risk before the certificate is obtained:

①过程>>> 服务或审核过程不合规，造成甲方的证书问题。【应对措施：乙方应严格按照国家认监委的合法规则进行认证过程控制，不得简化流程、违规操作、弄虚作假】

The process >>> The certification or audit process is not compliant, affect party a's certificate issue. 【Response measures: Party b shall, in strict accordance with the legal rules of the national supervision and administration commission, control the certification process, It is not allowed to simplify the process, operate illegally, and falsification】

②机构>>> 服务机构不合规，造成甲方的证书问题。【应对措施：乙方应严格按照国家认监委的合法规则推荐国家认监委认可的合法服务公司，不推荐非法审核公司、并保证认证证书来自正规渠道】

Mechanism >>> The certification or audit process is not compliant, affect party a's certificate issue. 【Response measures: Party b shall, in strict accordance with the legal rules of the national supervision and administration commission, to recommend the legitimate audit companies approved by the national committee for the recognition of supervision and supervision, do not recommend illegal auditing companies、And ensure that the certificate is from the formal channel】

6.2、证书获得后的风险/The risk after the certificate is obtained:

①过程>>> 获证后甲方应长期延续相关记录，并做好持续改进，以免在国家抽查时，因未认真落实而取消或暂停而影响证书的正常使用【应对措施：甲方应按乙方的要求在获证后长期贯彻执行，有能力的企业可与乙方签定年度凭用合同，月月跟踪，以确保有效性、持续性】；

The process >>>After the certification, party a shall keep the relevant records for the long term, and make continuous improvement, in case of national sampling, It is cancelled or suspended because it is not implemented seriously and affect the normal use of the certificate【Countermeasures: Party a shall, upon the request of party b, carry out its execution for a long time after it has been certified, the competent enterprise may sign the annual contract with party b, month to track, to ensure effectiveness and sustainability】

②机构>>> 机构的暂停、注消、撤消或国际规则变更等导致获得的证书失效【应对措施：乙方保证获证时机构的合法性及有效性控制】

Mechanism >>> The suspension, cancellation, withdrawal, or international rule change of the certification authority results in the failure of certificates or changes in international rules 【Response measures: Party b guarantees the legitimacy and effectiveness of the institution】

## 7、我公司承诺 / Secretly promise

7.1 保密承诺

7.1.1 乙方相关人员严格遵守职业道德，未经甲方书面授权或许可，不得将甲方经营、生产状况及技

术信息等以任何方式泄露给第三方，但下列情况除外：

Party B related personnel should be strictly obey professional ethics, without the written authorization or permission, Party A shall not disclose management, production status and technical information to the third party in any way. But except for the following situations:

7.1.2 本协议签署前乙方得到的信息。Party B got the information before signing the agreement.

7.1.3 甲方已公开的资料。Party A already in the public information.

7.1.4 法律法规另有要求或国家主管部门要求时。Laws and regulations have requires or national authorities have requirement.

## 7.2 合法性承诺

甲方委托乙方代为办理的所有认证，均出自正规渠道，且都是获得了国家及国际市场认可。

All the certifications handled by Party B on behalf of Party A originate from formal channels and have been recognized by national and international markets.

## 8、协议的生效、变更与终止 / Enforcement, change and termination of the agreement.

8.1 在协议执行期间，若有变更或补充内容，经双方协商同意后以书面附件的形式记录，且附件作为本协议不可分割的组成部分与本协议具有同等的法律效力。

During the execution of the agreement, if change or supplement the content of the agreement by mutual consultations in the form of a written record of the annex, and the annex has the same legal effect with this agreement ,as an integral part of this agreement.

8.2 本协议一式二份，甲乙双方各执一份，具有同等的法律效力，自双方签字之日起生效，本项目完成时此协议终止。

A duplicate of this Agreement, each party shall hold one copy with the same legal effect. Go into effect since the date signed by both parties, the termination of this agreement when the project is completed.

## 9、违约责任 / Liability for Breach of Contract.

9.1 双方未经协商而单方终止协议，违约方应向损失方支付违约金，违约金为协议总费用之20%。

Both parties terminate the agreement unilaterally without consultation. Defaulting party should pay the penalty which is 20% of the total cost of this agreement to another party.

9.2 甲方未按预定计划完成相应义务，导致本项目未能及时完成，其后果由甲方承担；甲方没有及时向乙方支付服务服务费，其后果由甲方自行承担。

Party A fails to finish scheduled corresponding obligations, resulting in delaying in the completion of this project. And the consequences borne by the Party A. Party A doesn't pay the consulting service fees to Party B timely, and the consequences borne by the Party A itself.

9.3 乙方未按计划给甲方进行指导，导致本项目未能完成，应由乙方承担相应责任。

Party B fails to provide guidance according to the plan resulting in failure to complete this project. The relevant responsibility should be held by Party B.

## 10、争议处理 / Settlement of Disputes.

在协议履行过程中发生争议，双方应当协商解决，如达不成共识，可以申请当地仲裁委员会仲裁，或者按司法程序解决。

When dispute appears in the procedure of implementation the agreement, both parties should resolve through consultation. If both sides can't reach common perspective, they can apply for a local arbitration committee for arbitration or by the judicial settlement procedure.

## 11、合同查询与一致性声明 / Contract Search & Conformance Statement

本合同中英文的条款不一致时，以中文版本为准。

Especially Declare: case there is any discrepancy between Chinese VERSION AND English version, the Chinese version should prevail.

## 12、其它事项 / Other things.

甲方/Party A: 浙江仁川医疗器械有限公司

地址/ Address: \_\_\_\_\_

代表签字（负责人/representative）：  
\_\_\_\_\_

手机/ Mobile: \_\_\_\_\_

电话/Telephone: \_\_\_\_\_

传真/Fax: \_\_\_\_\_

盖 章/Stamp: \_\_\_\_\_

乙方/Party B: 源引力检测认证有限公司

地址/ Address: 温州市鹿城区双屿康华路口 1-1402 室

联络代表/Project representative:  


联络分支/Which branches: 温州分公司

手机/ Mobile: 13906646362

法人/President: 曾小波

盖章/Stamp: 





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手机/ Mobile: \_\_\_\_\_

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传真/Fax: \_\_\_\_\_

盖章/Stamp: \_\_\_\_\_



乙方/Party B: 源引力检测认证有限公司

地址/ Address: 温州市鹿城区双屿康华路口 1-1402 室

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合同编号: **31025916**

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