

## 《US Agent AGREEMENT》

NO. FDA2023-01

**Party A: Shenzhen Jamr Technology Co., Ltd.****Add: A101-301, D101-201, Jamr Science & Technology Park, No. 2 Guiyuan Road, Guixiang Community, Guanlan Street, Longhua District, Shenzhen Guangdong, CN 518100****Tel: +86-755-27982057****Fax: +86-755-61673107****http: www.jiemeirui.com****E-mail: RA.dept@jamrmed.com**

甲方: 深圳市捷美瑞科技有限公司

地址: 广东省深圳市龙华区观澜街道桂香社区桂圆路 2 号捷美瑞科技园 A101-301、D101-201

电话: +86-755-27982057

传真: +86-755-61673107

**Party B: Performance International, Inc.****Add: 2816 Sunset Ave., Rocky Mount, NC 27804, USA****Tel: 001-919-859-0478****Fax: 001-919-859-0478****E-mail: ybx99@yahoo.com**

乙方: 国际运作有限公司

地址: 2816 Sunset Ave., Rocky Mount, NC 27804, USA

电话: 001-919-859-0478

传真: 001-919-859-0478

Party A hereby appoints Party B as United States Agent and Party B accepts the appointment to be the authorized United States Agent for Party A in the market of United States. Both parties enter this agreement as follow:

甲方任命乙方为美国市场代表, 乙方接受甲方任命, 为甲方在美国市场的授权代表。双方签署下列协议:

**Party A**

甲方

1. Party A assures to provide their updated product list of all products which are sold in United States market to Party B.  
甲方确保向乙方提供最新的其在美国市场销售的产品清单。
2. If there are any changes of products, or Party A 's important information (e.g. address, telephone number, fax number, email, contact person), party A shall notify party B at once.  
如果产品, 或工厂相关信息 (例如: 地址, 电话, 传真, 邮件, 联系人) 有任何改变, 甲方必须适时通知乙方。
3. Assisting the Party B to respond to questions concerning Party A's products that are imported or offered for import into the United States.  
如果乙方遇到有关针对进口到美国市场的甲方产品的任何问题时, 甲方应协助乙方做出回答。
4. Party A shall be responsible for any business dispute such as claim for compensation caused by medical accident after sale, party B shall handle the dispute in accordance with the authorization of party A. All the expenses which should be confirmed by party A occurred during the party B's handling of the accident shall be borne by party A.



甲方应对销售后发生的任何医疗事故或质量索赔等业务纠纷负责。乙方根据甲方的授权，协助甲方联络处理。在事故处理中乙方支付的相关费用需甲方确认后由甲方承担。

5. After receiving the inspection scheduling requirement from FDA, Party A shall assisting Party B, according to FDA's requirements, present the inspection Schedule to Party B to be passed on to FDA for review and confirmation within 3 business days.

甲方对美国食品药品监督管理局要求制定检查甲方工厂的时间表的指令，甲方须在三个工作日内按美国食品药品监督管理局的要求配合乙方制定出检查时间表并提供乙方转交美国食品药品监督管理局审定。

## Party B

### A. 乙方

1. Party B shall be responsible for assisting FDA in communications with Party A in time.  
乙方须负责协助美国食品药品监督管理局与甲方及时联络沟通。
2. Party B, under the assistance of Party A, shall respond to questions from FDA concerning Party A's products that are imported or offered for import into the United States.  
乙方在甲方的协助下负责对进口到美国的甲方产品的FDA问题做出回应。
3. Party B shall assisting FDA in scheduling inspections of Party A.  
乙方须协助美国食品药品监督管理局制定对甲方进行工厂检查的时间表。
4. Party B shall retain all information supplied by Party A and take up the responsibility of confidentiality.  
乙方应保留甲方提供的所有信息，并负保密责任。
5. Party B shall notify any information about the products of Party A sold in United States including customer's complaints and any information from competitors.  
乙方应将获得的有关甲方产品在美国市场的任何消息(包括客户投诉和同类竞争企业)及时通知甲方。

### B. Absent a separate agreement to the contrary, Agent shall NOT:

除非有另外协议，乙方不应承担下列义务：

1. Provide any legal advice on any matters of conflict with FDA or advise Company on issues of compliance with FDA Quality System Regulations such as in the design, manufacture, packaging, labeling, storage, installation, servicing and records keeping, etc.  
如果甲方与FDA在任何问题上发生争执，乙方不应提供任何法律咨询。乙方也不应在产品的设计，生产，包装，标签，储存，安装，维修和产品档案的保存等FDA所要求的质量系统管理和控制的问题上为甲方提供建议。
2. Provide any services relative to the administration of FDA required reports under the Medical Device Reporting regulation, (*under the regulation, the manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, must establish and maintain adverse event files, and must submit to FDA specified followup and summary reports,*

and etc.) Party B can only, as necessary, facilitate communications between the FDA and Company as contemplated by the Regulation.

在FDA规定的医疗器材事故报告制度上，乙方不提供任何行政方面的服务，除了需要时，就此事促成FDA和甲方的双向联系。（在这个报告制度下，工厂必须向FDA报告其产品造成或者可能造成的死亡或伤亡事故，工厂必须保存这些事故的档案，工厂必须提供给FDA一份事故处理结果和总结报告，等等）

2. Provide assistance in any way regarding the preparation or filing of any documents with FDA regarding pre-market approvals or supplements, pre-market notifications, investigational device exemptions.

乙方没有义务协助甲方向FDA申请其产品进口到美国的许可证及其有手续。

3. Provide any services relative to the translation of Party A's products information such as written material of the products, manufacturing procedures, quality control system, etc. except as necessary to facilitate communications between the FDA and Party A on these matters.

有关甲方的产品介绍，生产过程，质量控制等一系列问题，乙方不提供翻译服务。除了需要时，就这些事促成FDA与甲方的联系。

As agreed by both parties, this agreement shall be valid for 5 years from February 6, 2023 to February 5, 2028. Party A shall pay off the service fee RMB 15,000 for Party B within 30 work days after the signature date of this agreement. The valid term of this agreement can be also determined separately.

Party A and Party B has no other rights and obligations than this agreement.

经商定，上述协议有效期为5年，有效期限为2023年2月6日至2028年2月5日。在签约之后的30个工作日内，甲方一次性付给乙方代表费人民币15,000元整。

协议有效期限也可由甲，乙双方共同商定。

除本协议外，甲、乙双方不赋予其他权利和义务。

付款帐号：上海欧集进出口有限公司

开户行：招商银行股份有限公司上海北外滩支行


帐号：121910606310901

Party A: Shenzhen Jamr Technology Co., Ltd.

甲方：深圳市捷美瑞科技有限公司

(Signature and date)

(签字及日期)

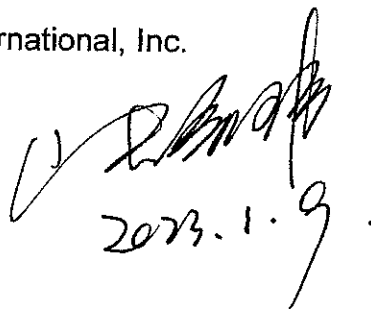
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Party B: Performance International, Inc.

乙方：国际运作有限公司

(Signature and date)

(签字及日期)

 2023.1.9