

Statement

This product Digital Intraoral Scanner System (S7000) is not a covered product and has no association with the manufacturer of the covered product.

This product is authorized SHARE INFO INC.(Address:3557 158th St Flushing, NY 11358, USA)to be the United States agent.

Annex: US Agent Aggrement

Fussen Technology Co.,Ltd.

2023-2-24

甲方:

Part A:

公司名: Name:	深圳市菲森科技有限公司 FUSSEN TECHNOLOGY CO., LTD
地址: Address:	深圳市南山区桃源街道平山社区流线大道1189号红花岭工业区第4区闽利达工业大厦B栋3层 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen Guangdong, CN 518055
电话: Tel:	18129964820
联系人: Contact person:	李慧君 Huijun Li
电子邮箱 E-mail:	registration@fussengroup.com

乙方:

Party B:

公司名: Name:	SHARE INFO INC.
地址: Address:	3557 158th St Flushing, NY 11358, USA
联系人: Contact person:	Clare
电子邮箱 E-mail:	us-agent@share-info.com

Party B acts as the US agent for Party A, Party B accepts the appointment to be the U.S. Agent for Party A for the legally listing products in the U.S. Food and Drug Administration (FDA) Both parties enter this agreement as follow: 甲方任命乙方为其 FDA 美国代理人 (US agent), 乙方接受甲方任命为甲方在美国食品和药物管理局 (FDA) 已合法登记的医疗产品的美国代理人 (US agent), 双方签署如下协议:

Party A

1. Party A assures to provide the updated product list and relative information to Party B. 甲方确保向

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乙方提供最新的产品列表和相关信息。

2. If there are any changes of products, Party A shall notify Party B with change notification in electronic copy as soon as possible. 产品如有改变, 用电子文档及时通知乙方。
3. Party A shall communicate with FDA with the assistance of Party B if needed. 如需要, 甲方通过乙方的协助和FDA进行沟通。
4. Party A should appoint one or two persons as the primacy linkman who connect with Party B to coordinate and deal with normal daily work according to this agreement. 甲方需指定一至两人, 作为甲、乙双方的第一联络人, 主要职责是与乙方共同协调、处理本协议条款规定范围内的日常工作。
5. Party A shall fully realize the risk of selling its products in the U.S market without premarket approval or notification. If it is caused by Party A, such as delay, omittance or conceal of files submission, Party A should take the aftereffects such as warning and penalty, and the distribution of its products in the U.S market will be prohibited. 甲方需要充分认识到本企业产品由于迟缓、延误、疏漏或者隐瞒而造成产品没有上市前审批或上市前通知就销售美国市场必定带来的风险。如果由于甲方的原因, 发生产品没有登记备案就进入美国市场的, 甲方将承担罚款、警告, 和禁止产品进入美国市场的后果。

Party B

1. Assisting FDA in communications with the foreign establishment; 协助 FDA 与甲方沟通;
2. Responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States; 回答甲方一些关于进口或者提供进口到美国的相关问题;
3. Assisting FDA in scheduling inspections of the foreign establishment and if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment. 协助 FDA 向甲方转达审核时间的通知, 如果 FDA 无法与甲方进行直接高效的沟通, FDA可以向乙方提供信息或者文件, 此行为等同于 FDA 向甲方提供相同的信息和文件。

Please note that the U.S. agent has no responsibility related to reporting of adverse events under the Medical Device Reporting regulation (21 CFR Part 803), or submitting 510(k) Premarket Notifications (21 CFR Part 807, Subpart E). 请注意, 乙方没有责任按医疗器械报告规定(21 CFR Part 803)向 FDA 报告不良事件, 也没有责任代替甲方向 FDA 递交 510k 申请(21 CFR Part 807, Subpart E)。

The validation of this agreement is 2023-12-31, During the implementation of the agreement, this agreement will be terminated automatically when: 本协议有效期至2023年12月31日。在协议期内, 发生下列内容协议将自动失效:

1. The day upon Party A cancels all of its Establishment registration and device listing in FDA.
甲方取消在FDA的所有场地注册和产品列名。

Both parties agree to use their best reasonable efforts to resolve all disputes, controversies and differences in connection with this agreement in an amicable manner. If the settlement fails to be reached, all the disputes arising from or in connection with this agreement shall be submitted to Guangzhou Arbitration Commission for arbitration, which shall be conducted in accordance with the arbitration rules in effect at the time of applying for arbitration. The arbitration award is final and binding upon both parties. The arbitration shall be conducted in Chinese, and the number of arbitrators shall be three, and the place of arbitration shall be Guangzhou P. R. China.

双方同意尽其最大的合理努力以友好方式解决与本协议有关的所有争议, 争论和分歧。如果未能达成和解, 则因本协议引起的或与之有关的所有争议应提交广州仲裁委员会进行仲裁, 该仲裁应按照申请时有效的仲裁规则进行。仲裁裁决是终局裁决, 对双方均具有约束力。仲裁应以中文进行, 仲裁员应为三名, 仲裁地点为中国广州。

The two sides signed the agreement on the following dates as proof.
双方于下列日期签署本合同, 以资证明。

甲方:
(Party A) 深圳市菲森科技有限公司
FUSSEN TECHNOLOGY CO., LTD.
地址: 深圳市南山区桃源街道平山社区流线大道1189号红花岭工业区第4区闽利达工业大厦B栋3层
(Address) 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen Guangdong, CN 518055

乙方:
(Party B) SHARE INFO INC.
地址: 3557 158th St Flushing, NY 11358, USA
(Address)

For and on behalf of
SHARE-INFO INC.

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Authorized Signature(s)

单位盖章:
(Seal)

日期(Date): 年(Y) 月(M) 日(D)

单位盖章:
(Seal)

日期(Date): 2022 年(Y) 12 月(M) 15 日(D)

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(Appendix 1)

附件 (一) :

For the following Product categories:

申请产品列表:

No.	Product name	中文名称	产品分类	型号清单 List of models	产品代码 Product Code
1	Fussen, Digital Intraoral Scanner System S6000	/	II	/	NOF

There is no content below.

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Authorized

美代协议编号 / US Agent Agreement No. : UA221206-0004 V1.1

甲方:

Part A:

公司名: Name:	深圳市菲森科技有限公司 FUSSEN TECHNOLOGY CO., LTD
地址: Address:	深圳市南山区桃源街道平山社区流线大道1189号红花岭工业区第4区闽利达工业大厦B栋3层 3F, Building #B, Minlida Industrial Building, Zone 4, Honghualing Industrial Zone, 1189 Liuxian Avenue, Pingshan Community, Taoyuan Street, Nanshan District, Shenzhen Guangdong, CN 518055
电话: Tel:	18129964820
联系人: Contact person:	李慧君 Huijun Li
电子邮箱 E-mail:	registration@fussengroup.com

乙方:

Party B:

公司名: Name:	SHARE INFO INC.
地址: Address:	3557 158th St Flushing, NY 11358, USA
联系人: Contact person:	Clare
电子邮箱 E-mail:	us-agent@share-info.com



根据原协议 UA221206-0004, 双方做如下修改:

According to the original agreement UA221206-0004, the two parties made the following modifications:

For and on behalf of
SHARE-I

1) 产品列表为:

List of products:

No.	Product name	中文名称	产品分类	型号清单 List of models	产品代码 Product Code
1	Fussen, Digital Intraoral Scanner System S6000	/	II	/	NOF

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修改为:

Modifications:

No.	Product name	中文名称	产品分类	型号清单	产品代码
				List of models	Product Code
1	Fussen, Digital Intraoral Scanner System	/	II	S6000, S7000, S7000 Premium	NOF

原协议中其他条款内容保持不变

Other terms in the original agreement remain unchanged.

Party A:


李德仁 2023.2.24
(甲方签章和签名/ Stamp & Signature)

(日期/Date)

Party B:

For and on
SHARE-INFO INC.

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Authorized Signature(s) 2023.02.24

(乙方签章和签名/ Stamp & Signature)

(日期/Date)

INFO INC.

Authorized Signature(s)

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