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# MDR EU REP Agreement

**Party A甲方:** ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO., LTD

**Add地址:** No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China .

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**Party B乙方: *SUNGO Europe B.V.***

**VAT：NL857821659B01**

**Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands**

**Contact联系人: SUNGO Secretary**

**Tel电话/Fax传真: +31（0）2021 11106**

**E-mail邮箱: ec.rep@sungogroup.com**

Party A hereby appoints Party B as the EU authorized Representative for their Medical Device with CE mark and Party B accepts the appointment to be the EU authorized Representative for Party A in the market of European Union (E.U.). Both parties enter this agreement as follow:
甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命,为甲方在欧盟市场的CE医疗产品授权代表。双方签署下列协议：

## 1. Party A 甲方

1.1 Party A assures to provide the updated technical files of each product category with CE mark to Party B (Product categories relevant information please see the appendix A). If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/TXT version), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files in appendix B.
甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档（甲方申请CE认证的产品信息见附录一）。如果甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此而引起的所有后果。甲方必需提交电子文挡文件，文件可以PDF/WORD/JPG/TXT格式的任何一种提交。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文档内容的要求，详见本协议"附件二"。

1.2 Party A shall keep the Party B informed of any changes or updates of the mentioned information in attachment 1 at all times.
如果附件1中的文件有任何变化或更新，甲方应及时通知乙方。

1.3 If any accident/near accident of products, including any serious adverse event during clinical

investigation in premarket stage, happens within boundary of E.U., Party A shall help Party B to investigate the reason in time, and complete & submit the initial INCIDENT report together with Party B by using the standard "Manufacturer's Incident Report", to the competent Authority within the timeframe required by the Section 5.1.7 of Guideline's on a Medical Devices Vigilance System(MEDDEV 2.12-1 rev8, Jan, 2013), listed as follows:
如果产品在欧盟境内发生事故或者准事故（包括在上市前的临床调查阶段发生的严重不良事故），甲方应及时配合乙方调查原因，并同乙方一起在下列医疗器械警戒系统指南（MEDDEV 2.12-1 rev8, Jan, 2013）Section 5.1.7 中规定的期限内完成和提交初始报告。
Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by Party A of this threat.
严重威胁公共卫生安全：立即报告（不允许任何无正当理由的延误），报告时限是不应迟于甲方发现该威胁后2个自然日。
Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after party A established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness.
死亡或意外的健康状况严重恶化：立即报告（不允许任何无正当理由延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起10个自然日。
Others: IMMEDIATELY (without any delay that could not be justified) after Party A established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.
其他：立即报告（不允许任何无正当理由的延误），报告时限是甲方在确认医疗器械和事故关联后，但是不应迟于从发现该事件之日起30个自然日。

Party A shall present the investigation result and final report to Party B according to MDR(REGULATION (EU) 2017/745) (MDR products) and the Guidance of vigilance system. If the accident of the product happens out of E.U., Party A shall notify Party B as soon as possible, and Part B should make decision whether to report to competent authority or not.
甲方应在《欧洲共同体理事会法令》按MDR 2017/745 （MDR产品）和《警戒系统指南》规定的时间内向乙方报告调查结果和最终报告。如带CE标志的产品，其事故、准事故发生在欧盟境外，甲方应尽快告知乙方，并由乙方决定是否向主管当局报告。

If the above mentioned accident/near accident of products was known by Party A at first, Party A must notify Party B in one working day and provide the complete report of the investigation, analysis and disposal result of the accident/near accident to Party B by E-mail or other effective means as soon as possible.
如果上述事故、准事故是通过甲方渠道先期获得的，甲方须立即在一个工作日内转告乙方；然后，对事故、准事故的调查、分析和处理结果的报告，用电子邮件或其他有效的方式尽快通知乙方。

1.4 Party A should keep the complete sales list of all of the products exporting to any area of E.U. by electrical documents in English at least 10 years after the last batch product's manufacturing, in order to be provided by Party B for the using to be transferred or inspected to the relevant competent authorities of E.U., Party A shall assure the accuracy and the validity of the data.
甲方出口欧盟地区的所有产品的销售清单（包括OEM的销售清单），在产品停产后至少十年期间，必须用英文文字、电子文档形式保留完整无缺，以备乙方随时用于欧盟官方的调用、检查。甲方应确保其提供的数据的准确性和真实性。

1.5 Party A must notice Party B the complaint record and the result of disposal on the accident of products immediately, and Party A should save, transfer, check-up any of the record according to the clause 1.4.
甲方针对客户/用户的事故或者准事故的投诉、抱怨记录和处理结果，除了应该及时通知乙方以外，所有记录的保存、调用、检查，按照1.4条款办理。

1.6 Party A should appoint one or two persons as the primacy linkman who connect with Party B and deal with the normal daily grind according to this agreement. Information of both Parties'

linkman should be written in appendix C.
甲方需指定一至二人，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。双方联络人的联络方式记录在本协议的附件（三）。

1.7 Party A shall fully realize the risk of selling its products to EU market without product registration to relevant competent authority of E.C. If it caused by Party A, such as delay, omittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU market will be prohibited.
甲方应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登记备案就销售欧盟市场带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入欧盟市场的，甲方将承担罚款、警告，甚至直至吊销CE产品证书和禁止产品进入欧盟市场的后果。

1.8 Part A shall notify of the intention to Part B to carry out a clinical investigation for MDR, or the intention to carry out a performance evaluation for IVDR performed in EU.
甲方应通知乙方在欧盟其对医疗器械进行临床试验的计划，或对体外诊断设备或试剂进行性能评估的计划。

## 2. Party B 乙方

2.1 About the register for Party A's products with CE mark to relevant competent authority of E.C. (Details are in appendix D), Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Netherlands) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly. The details of the application shall be in the attachments of this agreement. (The charges of products register in EU shall be paid accordingly by Party A and a contract may be signed separately if necessary.)
甲方已取得CE证书的产品按欧盟相关规定（详见协议附件四），必须需要办理CE产品欧盟登记备案的，需先由甲方提出申请，并提供所有符合规定的文件并填写申请表格，经乙方初步认可后，由乙方负责在7个工作日完成初审，5个工作日内提交乙方所在国荷兰主管当局审核申请登记备案的文件。但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请，不在此时间规定之列。提交文件的内容、时间等细节，应该在双方协议的附件中明示。（登记备案的费用甲乙方根据实际注册情况另外商议并签订合同）

If it needs any expenditure by the competent authority, only after getting Party A's approval, then Party A can take on the payment. If Party A's products register fails by Party B's reason, according to EU relevant laws Party B will be given a warning, penalty and even the qualification of the European Representative will be revoked.
如果需要任何主管机构审核上述登记备案如需要收取相关费用的，需经甲方同意方可由乙方代为支付。如果由于是乙方的原因，甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的，根据欧盟有关法律法规，乙方将受到警告、罚款、吊销担任欧盟代表资格的处罚。

2.2 Party B shall reserve technical files of each category of Party A's products with CE mark, and take up the responsibility of keeping, confidentiality and submission. The technical files shall be reserved at least 10 years after the last batch product's manufacturing. Once competent authority needs the technical files (including new edition technical files which had already registered) of each category of Part A's products with CE mark. Party B should send them to competent authority within ten working days.
乙方应保留甲方每一大类获得CE标志产品的技术电子版文档，并负保管、保密和提交当局的责任。该文档至少保存至最后一批产品停产十年后。一旦欧盟主管当局需要获得CE标识产品的技术文件（含已备案的技术文件的新版本），乙方负责在10个工作日内递交欧盟主管当局。

2.3 Party B would not be responsible for the file content. All the documents, such as sales list and complain records are deemed confidential information; Party B have the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.
乙方不对甲方提交的文件内容负责，乙方对甲方提供的销售清单、投诉记录等文件，负责递交欧

盟相关机构审阅并负有保管、保密的责任。

2.4 Party B permits Party A to use part B's name and address for the purpose of inclusion/printing on all packaging, labeling and instruction for use, of products that carry CE Marking and that have been represented by Party B.
乙方允许在被乙方代表的加贴CE标志的甲方产品的包装、标签、说明书、宣传册等上面加印乙方名称地址作为甲方的欧盟授权代表。

2.5 Party B shall keep following files of party A's products with CE mark at the disposal of the national authorities, at least five years after the last batch product's manufacturing. Minimum documents are:
1) Declaration of conformity,
2) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
3) Notified Body certificate (where relevant),
4) Post market surveillance process and data, vigilance reports and complaints, processes and data,
5) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
6) Relevant clinical data / notification,
7) Details of any distributors / suppliers putting the CE marked devices on the market,
8) Incident reports and corrective actions taken.
乙方应保留甲方以下与CE 标志产品有关的资料供主管当局使用， 至少保存至最后一批产品出厂后十年。这些资料至少应包括：
1)符合性声明
2)标签、包装、说明书副本（所有上市国家要求的语言的版本）
3)公告机构证书（适用时）
4)上市后监督过程和数据、警戒报告以及投诉、处理和数据
5)与欧盟成员国上市监督调查有关的技术文件
6)相关的临床数据/通知
7)经销甲方CE标志医疗器械的经销商/供方细节
8)事故报告及采取的纠正措施

2.6 Party B must keep Party A 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 following shall be covered.
乙方应通知甲方所有有关其在欧盟上市医疗器械的信息，至少包括:

2.6.1Safeguard Clause保护条款
"Where a Member State ascertains that a medical devices, when correctly installed, maintained and 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 Party B about its interim measures to withdraw Party A's device(s) from the market or prohibit or restrict their being placed on the market or put into service, Party B should immediately communicate such measures to Party A and advise Party A as to the implications of this decision.
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 his authorized representative".
If the relevant Competent Authority contacts Party B, Party B should immediately communicate such information to Party A and advise Party A as to the implications of this decision.
"当一个成员国确信一个医疗器械在正确安装、维护和按照预期用途使用情况下，可能会危害患者、使用者、（适用时）其他人员或财产的健康和/或安全时，应采取所有适当的临时措施以将医疗器械撤出市场、禁止或限制器上市"。

如果有关主管当局就有关对甲方医疗器械采取撤出市场、禁止或限制上市的临时措施联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。

当欧盟委员会认为国家的措施不合理，应立即通知采取措施的成员国、制造商或其欧盟授权代表。

如果有关主管当局联系乙方，乙方应立即将相关措施与甲方沟通，并向甲方建议此决定的相关影响。

2.6.2警戒Vigilance

If the relevant Competent Authority contacts Party B about its assessment outcome of an incident of Party A's medical device, Party B should immediately communicate such information to the manufacturer and advise Party A as to the implications of this decision.

如果欧盟主管当局通知了乙方关于甲方产品发生的事故的决定，乙方应立即就此联系甲方并且使甲方知晓主管当局的决定。

Party B shall notify any information about the products with CE mark within boundary of E.U. to Party A, including any claims of customers that produce the same CE marked products.

乙方应将获得的有关CE产品在欧盟境内的任何消息(包括客户投诉)及时通知甲方。

2.6.3If any accident/ near accident of products (CE marked products, premarket clinical investigation products and performance evaluation products) happens within boundary of E.U., Party B shall notify Party A within 3 working days after receiving the claims of customers and feedback about the product, and execute vigilance system of medical device products under the assisting of Party A, and also make initial report, investigation result and final report to competent authority of country in which the accident happens.

如果带有CE标志的产品，上市前临床试验的产品以及进行性能评估的产品在欧盟境内发生事故或者准事故，乙方应在收到或得知有关甲方产品的投诉或反馈信息3个工作日内及时通知甲方，并在甲方的协助之下调查原因，同甲方一起负责完成初始报告。乙方负责把完成的初始报告、调查结果和最终报告向欧盟主管当局提供。

2.7 Upon receiving the notice about the intention to carry out a clinical investigation for MDR, and the intention to carry out a performance evaluation for IVDR in EU, Party B shall notify communicate the information on the manufacturer and on the device to the Competent Authorities of the Member State in which he has his registered place of business. If any serious adverse events during clinical investigation, i.e. in the premarket phase, Party B Shall fully record and immediately notify to all Competent Authorities of the Member States in which the clinical investigation is being performed.

乙方需要在收到甲方关于在欧盟境内进行医疗器械的临床试验计划，和体外诊断设备或试剂的性能评估计划的通知后，需将相关信息通知所在国的主管机构CA。如果在临床调查中发生严重不良事件，乙方应及时对其进行完整记录并立即告知进行临床调查所在地的主管当局。

2.8 Party B shall appoint one or two persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in appendix C.

乙方需指定一至二人，作为甲、乙双方的第一联络人，主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的附件（三）。

## 3. Jurisdiction & Duration 管辖权与有效期

3.1 This agreement is subject to the laws and jurisdiction of The Kingdom of Netherlands.
本协议是荷兰的法律制约和管辖。

3.2 This agreement is valid for the duration till 2025/3/29 and it becomes immediately effective from the signature date of Company A.
该协议自甲方签署之日起立即生效，有效期至2025年3月29日。

3.3 During the implementation of the agreement, this agreement will be terminated automatically when:

在协议执行期间内，下列日期为本协议的自动终止日期：

1) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body.

甲方的CE证书因故被发证机构暂时吊销/关闭/收回之日：

2）Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or before using CE mark for "self declaration" products. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.

甲方在认证结束取得证书之后的30天内，或者"自我声明"产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效。在本失效之日起的60天内，为了能够方便甲方聘请新的欧盟代表及更改CE证书等相关工作，乙方可以代为继续行使欧盟代表日常事务。乙方应该将与甲方失效的协议信息及时报公告机构备案。

3）Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.

甲方没有按协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

***Company A:*** 23/06/2020
Date

Signature

***Company B:*** 22.6.23
Date

Signature

# Appendix A

For the following product categories:
申请CE认证的产品名称：

| No. | Product name 产品名称 | Product classification 产品分类 | Product name in Chinese 中文名称 |
|---|---|---|---|
| 1 | FACE MASK (MEDICAL) | CLASS I | 一次性医用无纺布口罩(医用)(非灭菌) |
| 2 | EMERGENCY STRETCHER&STRETCHER ACCESSORIES | CLASS I | 急救担架及担架配件 |
| 3 | HEAD IMMOBILIZER | CLASS I | 头部固定器 |
| 4 | VACUUM STRETCHER | CLASS I | 真空担架 |
| 5 | EXTRICATION DEVICE | CLASS I | 躯干夹板 |
| 6 | CERVICAL COLLAR | CLASS I | 颈托 |
| 7 | SPLINT | CLASS I | 夹板 |
| 8 | EMERGENCY TROLLEY | CLASS I | 急救推车 |
| 9 | EMERGENCY SCISSOR | CLASS I | 急救剪刀 |
| 10 | RESUSCITATOR | CLASS I | 呼吸器 |
| 11 | MANUAL SUCTION | CLASS I | 手动吸痰器 |
| 12 | EMERGENCY BLANKET | CLASS I | 急救毯 |



扫描全能王 创建

## Appendix B

提交欧盟代表的《技术文件目录》

| | Contents | 文件清单 |
|---|---|---|
| **Part A** | | |
| 1 | Name, Postal Address of Manufacturer/ EU Representative | 制造商和欧洲代表的名字、地址 |
| 2 | A listing of all manufacturing sites covered by the quality system | 质量体系所涉及的全部制造场所清单 |
| 3 | Product description | 产品描述 |
| 3.1 | Product name, classification of the device and accessories | 产品名字、器械及附件的分类 |
| 3.2 | List of accessories (if applicable) | 产品附件清单（适用时） |
| 3.3 | Specification, model and article numbers | 规格、型号及货号 |
| 3.4 | Chosen conformity assessment path | 符合性评价路径 |
| 3.5 | Intended use | 预期用途描述 |
| 3.6 | Integral parts of the sales unit | 主要的销售单元（适用时） |
| 3.7 | A brief product history (including existing regulatory approvals) | 简要的产品历史（包括现有的管理审批） |
| 4 | List of harmonized standards | 适用的标准清单 |
| 5 | GSPR checklist | 通用安全和性能要求检查表 |
| 6 | Overall manufacturing and inspection plan of the product | 产品的总体生产或质量控制方案 |
| 7 | Risk analysis | 风险分析 |
| 8 | Clinical report | 临床报告 |
| 9 | Labelling, inl. Product labels and package labels | 标签，包括产品标签、包装标签 |
| 10 | Instruction for use, patient information, advertising material | 使用说明、患者信息、广告材料 |
| 11 | Declaration of conformity | 符合性声明 |
| **Part B** | | |
| 12 | Information concerning the quality system specific to the product | 与产品有关的质量体系的信息 |
| 13 | Detailed descriptions of the product | 详细的产品描述 |
| 13.1 | Design drawings and product specifications | 设计图及产品技术规范 |
| 13.2 | Packaging and specification | 包装条件及规格 |
| 13.3 | Description of the manufacturing processes | 生产过程描述 |
| 13.4 | Raw materials and suppliers | 原材料和供方 |
| 14 | Test, verification and evaluation report | 试验、验证及评估报告 |
| 14.1 | Sterile method and validation | 灭菌方法和验证的概述，灭菌证书（适 |
| 14.2 | Packaging verification (if applicable) | 包装验证（适用时） |
| 14.3 | Chemical, physical and biology test, verification and evaluation report | 化学、物理和生物学试验、验证或评估报告 |
| 15 | Clinical datas | 临床数据 |
| 15.1 | Preclinical Evaluation, Expert Opinions | 临床前评估，专家意见 |
| 15.2 | Clinical plan | 临床方案 |
| 15.3 | Clinical datas | 临床数据 |
| 15.4 | Clinical Summary, Expert Opinions | 临床总结，专家意见 |
| 15.5 | Clinical report | 临床报告 |
| 15.6 | Relevant Literature | 相关文献 |
| 16 | Post market surveillance system | 上市后监管系统 |

A/B部分文件必须在需要时向欧盟代表处随时以书面或电子文档的形式提供最新版本；
Technical documents (the latest version) including Part A&B shall be submitted to the EU representative in written or electronic form if required.
B部分文件不限于以上所列项目。Documents in SUNGO are not limited to the above-mentioned content.

# Appendix C

《甲、乙双方第一通知人（联络人）以及联系方式》
Party A甲方: ZHANGJIAGANG XIEHE MEDICAL APPARATUS AND INSTRUMENTS CO., LTD
Add地址: No.7th, Middle Xinzha Road, Zhashang Industrial Zone, Yangshe Town, Zhangjiagang City, Jiangsu 215600, China
Contact联系人: Makiyo Liu
Tel电话: 0086-512-58175799
Mob手机: 15051708950
E-mail邮箱: sunshine@xieeh.com.cn

Party B乙方: SUNGO Europe B.V.
VAT：NL857821659B01
Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Contact联系人: SUNGO Secretary
Tel电话: +31(0)2021 11106
E-mail邮箱: ec.rep@sungogroup.com

备注事项：
甲、乙双方中的任何一方，一旦对上述信息做任何修改、调整或取消的，需书面/邮件方式及时通知对方。如果由于没有及时通知而造成一方的信息无法转达给另一方之错误的，由过错一方承担由此引起的相关责任。
If any of the above information is changed, adjusted or canceled, the manufacturer and EU REP shall inform the other party in email or written form without delay, If any mistake arise from one party failed to notify the other party timely, the related responsibility shall be undertaken by the guilty party.

# Appendix D

《CE产品欧盟登记备案的条件、程序及提交的文件》Registration conditions, procedure and submissions

一、申请的前提条件：Prerequisites of Application

1.生产商已经取得CE证书的产品（或者自我声明/公告的产品），是否办理欧盟地区产品登记备案手续，由生产商视本企业CE产品出口欧盟地区的实际情况，自行决定是否需要办理此项手续。The manufacturer who has obtained CE certificate（self declaration or issued by Notified Body) for their products may decide whether to go through the registration procedure according to the actual exporting situation in the European Union.

2.但是，如果生产商CE产品一旦有出口欧盟市场计划，且产品是以企业自己的名义出口欧盟市场的，根据欧盟对CE医疗器械产品的准入规定，生产商必须事先向欧盟代表提出申请，由欧盟代表代为提交所有的申请文件。这里所谓“以企业自己的名义出口欧盟市场”的含义是指：任何销售到欧盟地区的CE产品，在产品的任何之处（含产品内、外包装、说明书等），出现制造商任何信息的，既为“以企业自己的名义出口欧盟市场”，该企业的产品必须事先在欧盟申请办理登记备案手续。否则，由此而引起的后果，由生产商承担。

But, if the manufacture plans to export products to EU market and exports in their own name, the manufacture shall apply to the EU REP firstly according to the CE product access rule of medical device, and then the EU REP shall submit all the application files. 'Export to the EU market in manufacturer's own name' means the manufacturer's information showed on any place (including product inside, outer package, operation manual, etc.) of any CE products exported to EU region. The product must apply for registration in EU region in advance. Otherwise, the resulting consequences shall be undertaken by the manufacturer.

3.如果在荷兰申请登记备案成功，原则上无需再向欧盟其他国家和地区申请办理相关产品的登记备案手续。If successfully registered in the Netherlands, in principle, there is no need to apply for the relevant product registration in other EU countries and regions.

二、申请的程序：Application procedure:

1.如果生产商决定为CE产品办理登记备案手续的，生产商应首先向欧盟代表提出申请并按规定提交所有相关登记备案材料和填写申请表格，经欧盟代表审核认可后由欧盟代表代为向荷兰卫生主管当局提交相关申请登记备案材料。If the manufacturer decides to register the CE products, the manufacturer shall firstly apply to their EU REP and submit all relevant materials including completed application forms. The EU REP shall review the documents and then submit them to the Netherlands Health administration Bureau for registration.

2.如果由于生产商提交的材料不齐备或有误被荷兰卫生医疗主管部门退回而延误登记备案的，由生产商按照要求修订、补充申请材料以后，由欧盟代表办理再次申请手续。If the submitted documents are not complete or have errors, the Netherlands Health administration Bureau will return the application and may cause delay of the registration. The manufacturer shall revise and supplement the application documents according to the requirements, and then re-apply the CE registration through EU REP.

3.目前，荷兰卫生主管部门对相关的登记备案信息，采取有条件的开放，即尚未开通对所有公众查询上述登记备案信息的平台。At present, the Netherland Health administration Bureau conditionally open the relevant CE registration information which means the CE registration information platform is not yet open to public.

三、办理登记所需要的文件（英文电子版本）：Registration required documents (electronic version in English)

1.企业的书面申请表格；（格式由欧盟代表统一提供）Application form(the format provided by EU REP)

2.CE证书；CE Certificate;

3.每一大类产品的CE技术文件；（除了PART A部分以外，临床数据、风险管理等内容是必需的；文件格式只接受电子PDF/JPG/TXT）；each product categories CE technical file (except Part A, Clinical data and risk management must be submitted; documents only accept electronic copy (PDF/JPG/TXT version).

4.产品最近的符合性声明（latest DECLARATION OF CONFORMITY）；

5.出口欧盟地区的销售清单；（格式由欧盟代表统一提供）Product sales list exported to EU market.(the format provided by EU REP)
6.企业合法拥有的商标或品牌的图案实样照片；Legally owned enterprise trademark or brand photos;
7.出口原包装实样和带CE标志产品标签的照片；Picture of exported product in original package and label with CE mark.
8.企业联系人及联络方式；企业网站地址。Contact information and website.

四、登记的撤消与失效：Withdraw and invalidation of registration
1.CE证书失效或因故被发证机构吊销、关闭、收回；CE certificate invalid or withdrew or canceled by releasing authority.
2.生产商、欧盟代表双方就《欧盟代表协议》的中止或失效；Termination or expiration of EC REP Agreement.
3.企业已登记备案产品，长期没有出口欧盟地区的记录；The product has been registered but there is no record of exporting to the EU region in a long-term.
4.其他。Others