EU AUTHORISED REPRESENTATIVE'S MANDATE
欧盟代表协议

NO. M/A2022-3-24
欧盟代表协议

Start of the authorization: March 24, 2022
授权起始日期： 2022 年 3 月 24 日
Expire date of the authorization: March 23, 2027
授权终止日期：2027 年 3 月 23 日

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Party A hereby designates Party B as the authorised representative for their devices with CE mark and Party B accepts the designation to be the authorised representative for the devices on the market of European Union（E.U.）,EEA and Switzerland, Turkey. Both parties enter this mandate as follow:
甲方任命乙方为其 CE 医疗产品欧盟及 EEA 和瑞士、土耳其之授权代表，乙方接受甲方任命，为这些产品在欧盟及 EEA 和瑞士、土耳其之市场的授权代表。双方签署下列协议：

Party A
甲方

1. Party A shall 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. Party A shall ensure that Party B has the necessary documentation permanently available. If Party A fails to provide the above mentioned documentation to Party B within 30 days after approval of CE certification or before using CE mark for "self-declaration" products, this mandate will be terminated automatically, Party A should take on all aftereffects by itself. The technical documentations should be in electronic copies (in any of PDF, WORD, JPG, TXT vision), the written copies would be submitted if required by the competent authorities. List of the documentation is as per annex 1 of the mandate. Party A shall notify Party B the amendments and supplements of the documentations by means of electronic copies in time.
甲方应保存产品技术文件、欧盟符合性声明以及任何相关证书的副本（包括任何修正和补充）的期限，至少是该产品最后投放欧盟市场后的 10 年，产品如是植入的，则至少 15 年。甲方应确保乙方总能使用必要文件。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，文件可以是 PDF、WORD、JPG、TXT 格式中的任何一种。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"附件一"。技术文件如有更新及补充的，甲方应用电子文档形式及时通知乙方。

2. Party A shall ensure to satisfy the request by the EU competent authorities, forwarded by Party B, for example samples or access to devices, providing with all the information and documentation necessary to demonstrate the conformity of the devices.
甲方应确保满足欧盟主管当局通过乙方提出的要求，如提供产品实样或告知取得产品的途径，提供所有能证明产品符合性的信息及文件等。

3. Party A shall have a system for recording and reporting of incidents and field safety corrective actions. If any accident or near accident of devices (including any serious adverse event during clinical investigation in premarket stage)（see clause A1.5 e of "Guideline for Authorized Representatives(MEDDEV 2.5/10)(January 2012)"）happens in the territory of EU, EEA and Switzerland, Turkey, Party A shall help Party B to investigate the reason in time, and complete the initial report together with Party B. Party A shall present the investigation result and final report to

Party B according to EU2017/745(MDR devices), EU2017/746 (IVDR devices) and the Guidance of Vigilance System. If the accident of the devices happens out of EU market, Party A shall notify Party B as soon as possible, and Party B shall make decision whether to report it to the competent authorities or not. If the above mentioned accident or near accident of devices 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 or near accident to Party B by E-mail or other effective means as soon as possible.

甲方应拥有一个记录和报告事故以及现场安全纠正措施的系统。如果产品在欧盟境内及 EEA 和瑞士、土耳其之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（详见“Guideline for Authorized Representatives(MEDDEV 2.5/10)(2012 年 1 月)”），甲方应及时配合乙方调查原因，并同乙方一起负责完成初始报告。甲方应按 EU2017/745（医疗器械）或 EU2017/746（体外诊断器械）和《警戒系统指南》规定的时间内向乙方报告调查结果并提交最终报告。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。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。

4. Party A shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability of the possible defective devices. Party A shall be responsible for any business dispute related to their devices, such as medical accidents or claims for compensation concerning quality that arise after sale. Party B shall assist Party A to handle the dispute in accordance with the authorization of Party A. All the expenses occurred outside the China mainland during Party B's handling of the accident shall be borne by Party A. Party A should also pay all the costs of the traffics, accommodations and other allowances of party B’s employees or advisors, who make the business trips in China mainland subject to the requirements of investigation, analysis and disposal of the accident.

制造商应以与风险等级，产品类型和企业规模相称的方式，采取措施为他们可能缺陷产品的潜在责任提供足够的财务保障。甲方应对销售后发生的与其产品相关的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。在事故或索赔处理中，乙方需要在境外支付的相关费用，须经甲方确认后由甲方承担。如果由于调查、取证质量投诉、事故和索赔的需要，乙方雇员或顾问赴中国内地工作的，其食宿、交通等实际支出的费用，也应由甲方承担。

5. Party A should keep the complete sales list of all of the devices exporting to EU, EEA and Switzerland，Turkey (including the OEM devices) by electrical documentation in English at least 10 years after the last device has been placed on the market(15 years In the case of implantable

devices), in order to be provided by Party B for being transferred to or inspected by the relevant competent authorities of EU, EEA and Switzerland, Turkey. Party A is responsible for the accuracy and the validity of the data.
甲方出口欧盟地区及EEA和瑞士、土耳其之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10年（植入产品15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及EEA和瑞士、土耳其之官方的调用、检查。甲方要对提供的数据其准确性、真实性负责。

6. Party A must notice Party B the complaint records and the results of disposals on the accidents or near accidents of products immediately, and Party A should save, transfer, check-up any of the records according to the requirements of above article 5 of party A.
甲方针对客户/用户的事故或者准事故的投诉记录和处理结果，除了应及时通知乙方外，所有记录的保存、调用、检查，须参照上述甲方的第“5”条条款执行。

7. Party A shall appoint one or two persons as the main staff who contact with Party B and deal with the daily work according to this mandate. The information of these persons of both parties should be written in annex 3.
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”。

8. Party A shall fully realize the risk of selling its products to EU, EEA and Swiss, Turkey market without product registration to relevant competent authorities of EU. If it caused by Party A, such as delay, omission 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 frozen, withdrawn, and the distributions of its products in EU, EEA, and Swiss, Turkey market will be prohibited. The procedure and charges of products register in EU are written in annex 2 and annex 4. The EU MDR and IVDR have been implemented since May 2017, and according to which during the validity of this mandate, Party A shall fulfill the obligations of UDI assignment to the devices and the manufacturer and devices registration when the conditions are met.
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欧盟注册就销售欧盟市场及EEA和瑞士、土耳其之必定带来的风险。如果由于甲方的原因，发生产品没有欧盟注册就进入欧盟及EEA和瑞士、土耳其之市场的，甲方将承担由此可能产生的罚款、警告，直至被冻结甚至吊销产品CE证书及禁止产品进入欧盟市场及EEA和瑞士、土耳其的后果。CE产品/欧盟注册的详细程序和收费方法等内容，可参阅本协议“附件二”及“附件四”。欧盟MDR及IVDR法规已从2017年5月起施行，在本协议执行期间，甲方应在条件具备时，履行产品UDI分配及生产商和产品注册的义务。

9. Party A shall notify Party B of the intentions of clinical investigation trials for MD or AIMD, and the intention of the performance evaluations for IVD, which are to be performed in EU, EEA and Swiss, Turkey.
   甲方应通知乙方在欧盟、EEA 和瑞士及土耳其对医疗器械或者有源植入性医疗器械进行临床试验的计划，以及对体外诊断试剂进行性能评估的计划。
10. Party A's obligations laid down in regulation EU2017/745 article 10(1), (2), (3), (4), (6), (7), (9), (10), (11), (12) (EU2017/746 article 10(1), (2), (3), (4), (5), (6), (8), (9), (10), (11)) shall not be delegated by this mandate.
    欧盟 EU2017/745 法规第 10(1), (2), (3), (4), (6), (7), (9), (10), (11), (12)条款（欧盟 EU2017/746 法规第 10(1), (2), (3), (4), (5), (6), (8), (9), (10), (11)条款）所明确的制造商责任，甲方不得通过本协议委派。
11. Party A shall ensure Party B to pursue the loss afterwards if Party B was legally liable for defective devices on the same basis as, and jointly and severally with Party A due to Party A has not complied with the obligations laid down in regulation EU2017/745/746.
    如因甲方未遵守欧盟 EU2017/745/746 法规的制造商责任，致使乙方承担其缺陷产品的连带法律责任的，甲方应保证乙方可以事后追偿损失。

Party B
乙方

1. Regarding the EU registrations for Party A's products with CE marks, Party A shall apply it firstly in written to Party B and supply all the necessary files and fulfill the application forms (see details in attachment 2). Party B shall review it within 10 working days, and submit it to competent authority of the country in which Party B within another 10 working days. However, the time schedule should be adjusted If Party A's applications were returned or rejected by Party B or the above-mentioned competent authority due to inconsistent contents from the submitted files. If it is Party B's reasons causing Party A's products EU registrations failures, Party B will be given a warning, penalty and even its qualification of the European Representative will be revoked according to EU relevant laws. The EU MDR and IVDR have been implemented since May 2017, and according to which during the validity of this mandate, Party B shall fulfill the obligations of EU authorized representative registration and verify that Party A has complied with the registration obligations when the conditions are met.甲方已取得 CE 证书或自我声明的产品，按欧盟相关规定（详见协议附件二），需要办理 CE 产品欧盟注册的，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 10 个工作日完成初审，之后 10 个工作日内提交主管当局审核并申请产品注册。由于甲方提交文件内容不符等原因而被乙方或主管当局退回或拒绝的申请，不在上述时间规定之列。如果因乙方的原因，甲方申请产品注册手续失败而影响其产品正常进入欧盟市场销售的，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。欧盟 MDR 及 IVDR 法规已从 2017 年 5 月起施行，在本协议执行期间，乙方应在条件具备后，履行欧盟代表注册的义务并核实甲方也履行了生产商及产品注册义务。

2. Party B shall 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 Party A. Party B shall keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements at the disposal of competent authorities for the period of at least 10 years (15 years for implantable devices) after the last device has been placed on the market. Party B shall take up the responsibilities of confidentiality of the documentation and shall provide them within 10 days after the request of the competent authority.
乙方应核实甲方是否已经编制了产品欧盟符合性声明和技术文件，并在适用的情况下确认甲方已采取了适当的符合性评估程序。乙方应保存甲方产品的技术文件、欧盟符合性声明以及任何相关证书的副本（包括任何修正和补充），保存期限至少是该产品最后投放欧盟市场后的 10 年，产品如是植入的，则至少 15 年。乙方负责文件的保密，一旦主管当局需要，乙方负责在 10 个工作日内提交文件。

3. Party B shall keep the following minimum documentation of the devices of Party A with CE marks at the disposals of the competent authorities at least 10 years (15 years for implantable devices) after the last device has been placed on the market:
   i) Declaration of conformity,
   ii) Copy of the label, packaging and instructions for use (in all language requested by the countries where the device marketed),
   iii) Notified Body certification (where relevant),
   iv) Post market surveillance process and data, vigilance reports and complaints, processes, and data,
   v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
   vi) Relevant clinical data / notification,
   vii) Details of any distributors / suppliers putting the CE marked devices on the market,
   viii) Incident reports and corrective actions taken.

   乙方应至少将以下甲方产品的有关文件，至少保存至最后一批产品投放市场后 10 年（植入性产品 15 年），供各国主管当局调用。这些文档至少应包括：
   i) 符合性声明
   ii) 标签、包装、说明书副本（所有上市国家要求的语言的版本）
   iii) 公告机构证书（适用时）
   iv) 上市后监督过程和数据、警戒报告以及投诉、处理和数据
   v) 与欧盟成员国上市监督调查有关的技术文件
   vi) 相关的临床数据/通知
   vii) 经销甲方 CE 标志医疗器械的经销商/供方细节
   viii) 事故报告及采取的纠正措施

4. 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：

4.1 Safeguard Clause

"Where a Member State ascertains that a medical device, 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 devices 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 EU 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.

保护条款

"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、禁止或限制其上市"。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，并向甲方告知此决定的相关影响。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，乙方应立即将相关信息与甲方沟通，并告知此决定带来的相关影响。

4.2 Vigilance

If the relevant EU 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.

警戒

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评估结果，那么乙方应当立即就此联系甲方并使之知晓此决定的相关影响。

5. Party B shall notify promptly to Party A any information they could obtain about the Party A's devices with CE marks on the market (including about the claims of customers and the competition companies that produce the same CE marked devices). Party B shall forward to Party A any request by the EU competent authorities for samples or access to the devices and

verify that the competent authorities receive the samples or are given access to the devices. Party B shall response to a request from a competent authority, provide that 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. Party B shall also cooperate with EU competent authorities on any preventive or corrective action to eliminate or mitigate the risks posed by the product of Party A.

乙方应将获得的有关 CE 产品在欧盟市场上的任何信息(包括客户投诉和同类竞争企业)及时通知甲方。乙方应及时向甲方传递欧盟主管当局要求提供产品实样或告知取得产品的途径的信息，并确保主管当局获得实样或得知取得产品途径。乙方应响应主管当局要求，以有关成员国确定的官方正式语言，向该主管当局提供证明甲方产品符合性的所有必要信息和文件。乙方应配合欧盟主管当局采取针对甲方产品的预防或修正措施，用以消除或减小产品风险。

6. If any accident or near accident of the devices of Party A (including premarket clinical investigation devices and performance evaluation devices) happens in the territory of EU, EEA, and Switzerland, Turkey, Party B shall notify it to Party A within 3 working days after receiving or obtaining the customer's claims and feedbacks about the devices, and execute vigilance system under the assisting of Party A, and also make initial report, investigation result and final report to competent authority of the country in which the accident happens.

如果甲方的产品 (包括上市前临床试验的产品以及进行性能评估的产品)在欧盟及 EEA 和瑞士、土耳其之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。乙方负责将完成的初始报告、调查结果和最终报告递交给欧盟及 EEA 和瑞士、土耳其之主管当局。

7. Party B shall assist Party A to comprehend the devices' conditions of the same or relevant kind in EU market constantly. Party B shall also assist Party A in applying for a European certificate of free sale if party A needs and meets the requirements in accordance with article 60 of regulation EU2017/745 (or article 55 of regulation EU2017/746) .

乙方协助甲方了解欧盟市场同类产品的情况，并及时反馈给甲方。乙方还应按照欧盟 EU2017/745 法规第 60 条款(或欧盟 EU2017/746 法规第 55 条款)的规定，在甲方需要且符合条件时，协助甲方办理欧洲自由销售证明。

8. Party B shall appoint one or two persons as the main staff who contact with Party A and deal with the daily work according to this mandate. The information of these persons of both parties should be written in annex 3.

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”。

9. Party B shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union
乙方应在其机构内，永久拥有至少 1 位合规负责人员，该人员应具备欧盟境内医疗器械法规要求的必要专业知识。

10. Upon receiving the notice about the Party A's intention of the clinical investigation for MDD or AIMDD, or the intention of the performance evaluation for IVDD in EU, EEA and Swiss, Turkey, Party B should communicate this information to the Competent Authorities of the Member State where the investigations or the evaluations were being performed. If any serious adverse events happened during the above-mentioned performances, Party B should immediately set up an entire record to the event and submit it to the Competent Authorities as soon as possible.
乙方需要在收到甲方关于在欧盟、EEA 和瑞士及土耳其境内进行医疗器械或有源植入性医疗器械的临床试验计划，或体外诊断试剂的性能评估计划的通知后，将相关信息告知所在国的主管当局。如果在上述临床调查或性能评估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调查或评估的所在地的主管当局。

11. Party B who terminates the mandate due to the reasons in hereafter "Party A & Party B 1" shall immediately inform it with the EU competent authorities, if applicable the notified body involved in the conformity assessment for the products the termination of the agreement and the reasons therefor.
乙方如因以下"甲方及乙方 1"的原因中止本协议，应及时通知欧盟主管当局及相关公告机构，并阐明原因。

12. Without prejudice to article 10 of Party A of this mandate, Party B is fully aware that it could be legally liable for defective devices on the same basis as, and jointly and severally with Party A if Party A has not complied with the obligations laid down in regulation EU2017/745.
在不损害本协议甲方第 10 条款的前提下，乙方充分意识到会因甲方未遵守欧盟 EU2017/745 法规的制造商责任，而同甲方一起，承担其缺陷产品的连带法律责任。

Party A &Party B
甲方及乙方

1. This mandate will be terminated automatically when:
有任何下列情况发生，本协议自动终止：
   1.1) The Party A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notify body.
   (When the above-mentioned things happen, party A is obligated to

accomplish the following processes to avoid the further consequences:

i) Brief statement in written about the reasons why CE Certificate being withdrawn, being closed or being recalled by the notified body.

ii) Written statement of non-sales if there are no devices under the withdrawn, closed or recalled CE Certificate exporting to EU, EEA and Swiss, Turkey market, or if there are devices exporting, a written statement of sales would be required with the sales lists, risk assessments and the measures and timetable to cover the risk.)

甲方的 CE 证书因故被发证机构暂时吊销/关闭/收回的。

（以上事实一旦发生，甲方需主动配合乙方做好以下善后工作，否则将承担由于不作为或者作为不当而产生的所有责任：

i) 书面简要说明证书被吊销 / 关闭 / 收回的原因。包括更换公告机构的理由。

ii) 书面确认被取消的 CE 证书所有所列产品是否已经有出口欧盟市场以及 EEA 和瑞士、土耳其之市场。如果没有，请出具书面声明；如果有，请附上出口销售清单，同时请书面评估由此可能产生的风险并陈述甲方解决问题的措施和时间表。）

1.2) Party A has failed to provide the required technical documentation to party B within 30 days after approval of the CE certification or before using CE mark for “self-declaration” devices.

(Within 60 days from the date of this mandate being terminated, party B could transact the routine affairs as the authorized representative enabling Party A appointing new authorized representative and amending the CE Certification. Party B should report the invalidation of the mandate to the notify body for record.)

甲方在认证结束取得 CE 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。

（在本协议失效之日起的 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。）

1.3) Party A doesn’t pay off the representative service charge according to this mandate deadline without explanations.

甲方没有在协议规定的期限内付清欧盟代表服务费，又不作解释的。

1.4) Party A acts contrary to obligations under MDR/IVDR.

甲方有违反 MDR/IVDR 规定责任的。

2. When the mandate is terminated or not renewed upon expiration for some reason of both parties, Party A shall designate a new EU authorized representative if the CE certificate of their devices need to be continued. The three parties shall enter into an EU representative change agreement for handover matters.甲乙双方因故中止协议，或协议到期不再续签，而甲方产品仍然需要 CE 认证的，甲方应指定新的欧盟代表。三方应签署欧盟代表变更协议，约定具体交接事宜。

（The change agreement shall address at least the following aspects:

(a) The date of termination of the mandate of Party B and date of beginning of the mandate of the incoming authorized representative;

(b) The date until which Party B may be indicated in the information supplied by Party A, including any promotional material;

(c) The transfer of documents is realized by encrypting U disk or e-mail, Party B shall comply with confidentiality requirements and avoid infringement;

(d) The obligation of Party B after the end of the mandate to forward to Party A or incoming authorized representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorized representative.

(a) 乙方授权的终止日期，以及新任授权代表的授权开始日期；

(b) 甲方各种宣传材料使用乙方信息的截止日期；

(c) 文件传输通过加密的 U 盘或者电子邮件实现，乙方应遵守保密要求，并避免侵权；

(d) 授权结束后，乙方仍然有义务将来自医护专业人员、患者和使用者，与由授权代表指定器械相关可疑事件的投诉和举报转交给甲方或新任授权代表。

3. This mandate is written both in English and Chinese and in the event of any conflict between the two versions, Chinese version shall prevail.
本协议以中英文书写，如中英文版本存在任何冲突的，以中文为准。

4. The validation of this agreement is subject to the validation of CE Certificate for the devices under it, or is within five years after the signing of the mandate for the self-declared devices.
对于领取 CE 证书的产品，本协议有效期与产品 CE 证书一致；对于自我声明的产品，本协议自协议签订之日起五年有效。

5. Both parties agree to use their best reasonable efforts to resolve all disputes, controversies and differences in connection with this mandate in an amicable manner. If the settlement fails to be reached, the all the disputes arising from or in connection with this mandate shall be submitted to Shanghai International Economic and Trade Arbitration Commission (SHIAC) for arbitration, which shall be conducted in accordance with the arbitration rules in effect at the time of applying for arbitration. The arbitral award is final and binding upon both parties. The arbitration shall be conducted in English, the number of arbitrators shall be three, and the place of arbitration shall be Shanghai, 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上海国际经济贸易仲裁委员会（SCIA）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。 仲裁应以英文进行，仲裁员应为三名，仲裁地点为中国上海。

Enclosure:
附：

1. Name and classification of products Party A designates to Party B:
甲方任命乙方为欧盟代表的产品名称与类别:

No.	Product name 产品名称	classification 分类等级	GMDN 代码	Model 型号
1	Back support belt	MDR Class A		YQAH-1; YQAH-2 YGAH-1; YGAH-2 YQAH-3; YGAH-9 YGAH-5; YGAH-6 YGAH-8
2	Neck-traction device			JGAH-1; JQAH-4 JQAH-3; JQAH-6 JQAH-8
3	Lumbar traction device			JKAH-2; JKAH-2Y/T JKAH-4; JKAH-2M
4	Cervical care device			JKAH-3; JKAH-5
5	Neck brace			JGAH-5; JKAH-6
7	Knee care device			JKAH-1G, JKAH-1/S JKAH-1
8	Lumbar traction device			JKAH-2J
9	Lower back stretching massager			JKAH-2F
10	Neck air-traction device			JQAH-3B
11	Neck support			YGAH-5

2. Annex 1 《CE Technical Documentation List》
附件一 《提交欧盟代表的技术文档目录》
Annex 2 《Preparatory Requirements, Conditions and Procedures for CE Products registration in EU and the Update, Withdraw and the Invalidation of the registration》
附件二 《CE 产品申请注册的条件、时间、程序及所需提交的文档和已注册产品的更新、撤销与失效》
Annex 3 《Details of the Contacting persons of Party A and Party B》
附件三 《甲、乙双方第一通知人（联络人）以及联系方式》
The above three annexes shall have the same effect as the mandate.
以上三个附件与本协议具有同等效力。

3. Literature and regulations this mandate referenced:
1) Guidance of vigilance system (2.12-1 REV. 8 January 2013)
2) GUIDELINE FOR AUTHORISED REPRESENTATIVES <MEDDEV 2.5/10> (January 2012)
3) EU2017/745& EU2017/746
本协议参考、引用之文献、法规：
1）《警戒系统指南》（医疗器械指令 2.12-1 REV. 8 January 2013）
2）《GUIDELINE FOR AUTHORIZED REPRESENTATIVES <MEDDEV 2.5/10> 》(January 2012)
3) 《欧盟医疗器械法规》（EU2017/745）以及《欧盟体外诊断器械法规》（EU2017/746）
Note: in the validity of the mandate, it shall be executed always according to the latest issued versions of the above guidance, guideline and regulations in case of their modifications or updates and Party A and Party B are not necessary to sign a new a mandate.
备注：在协议有效期内，凡涉及以上法规修正 / 升级等变更的，按照新颁布的版本内容执行，甲、乙双方不再签订新的协议。

Party A: JIANGSU ALPHAY MEDICAL DEVICE CO., LTD.
甲方： 江苏安惠医疗器械有限公司

Signature and date：
签字及日期：2022 年 3 月 24 日

Party B: Everbiz GmbH
乙方： Everbiz GmbH

Signature and date：
签字及日期：2022 年 3 月 24 日

Annex 1 《CE Technical Documentation List》
(Soft Copy in English by PDF/WORD/JPG/TXT)
附件一《提交欧盟代表的技术文档目录》
（要求英文电子文档，PDF,WORD,JPG,TXT 格式中任何一种即可）

Part A （A 部分）

1) Manufacture's Name and its Address
生产商名称、地址
2) European Representative's Name and Address
欧盟代表名称、地址
3) Product's Trademark, Name, Model, Classification and rule of assessment
产品的商标名、品名、型号、分类及分类规则、认证途径
4) Name and Address of Manufacturing facilities
生产场地的名称、地址
5) Name and Address of Notify Body
公告机构的名称、地址
6) Declaration of Conformity (PDF with signature, stamp and date)
符合性声明（必须有签字、盖章及日期的 PDF 版本）
7) CE Certificate, Quality Assurance Certificate and Audit Report.
CE 证书，体系证书，审核员报告
8) Essential Requirements Check-list
基本要求检查表
9) A brief introduction to the product
产品的简要说明
10) Label and User's Instruction
标签语言、使用说明书
11) List of Harmonized Standards
使用的法规要求及标准（协调标准）
12) Introduction to testing and experiment, such as clinic, electrical safety, mechanical safety, performance and so on. Relevant report or validating record number (quoted from Part B) can be listed in the form of Requirements Check-list
有关的检测及试验的介绍，如临床、电气安全、机械安全、性能等，列出相关的报告或验证记录编号（引用 B 部分）,可以以基本要求检查表的形式列出

Part B （B 部分）

13)Risk Management Files
风险管理文档

14)Compilation of Clinic Data, Appraisal for Advantages and Disadvantages
临床资料汇编，利与弊评估

15)Vigilance System
警戒系统

16)Testing Reports (Biological Consistence, Physical Performance, Chemical Performance, Clinic and so on)
检测报告(生物相容性、物理性能、化学性能、临床等)

17)Description of Manufacturing Process, Manufacturing Process Flowchart, Description of Special Process, Crucial Control Point et.
生产过程描述，生产流程图，特殊过程描述，关键控制点等

The latest version of Part A/B shall be presented to European Representative immediately from time to time in case of modifications or updates and Part B is not limited to the above-said items.
上述 Part A/B 部分文档如有更新，应及时向欧盟代表提供最新版本的电子文档。Part B 部分文件不仅限于以上所列项目。

Everbiz GmbH
March 24, 2022　2022 年 3 月 24 日

Information Sources: NB Decision: NB-MED/2.5.1/Rec 5
文献来源：公告机构决议 NB-MED/2.5.1/Rec5

Annex 2 《Preparatory Requirements, Conditions and Procedures for CE Products registration in EU and the Update, Withdraw and the Invalidation of the registration》

附件二《CE 产品欧洲申请注册的条件、时间、程序及所需提交的文档和已注册产品的更新、撤销与失效》

I. Preparatory Requirements for CE Products registration in Germany/EU :
CE 产品申请注册的条件：

a. The products of Party A have been CE certified by Notify Body, or self-declared if the products classified as MDD class I (Non-sterile and Non-measuring) or IVDD class others.
甲方产品已经取得 CE 证书，或者一类产品已进行自我声明。

b. Party A as a manufacturer is for the first time intended to place their above-mentioned products on the market of EU, EEA and Swiss, Turkey, or intended to issue European “Certificate of Marketability” (“Free Sale Certificate”).
甲方产品拟首次进入欧盟、EEA 或瑞士、土耳其市场销售或甲方产品虽未拟进入欧盟、EEA 或瑞士、土耳其市场销售，但要求申请办理《欧洲自由销售证明》（有称“Certificate of Marketability” 或“Free Sale Certificate”）的。

2. Conditions for CE Products registration in Germany/EU:
CE 产品申请注册的时间：
At least 30days prior to place the products on the market of EU, EEA and Swiss, Turkey.
产品拟进入欧盟、EEA 或瑞士、土耳其市场前至少 30 天。

3. Procedures for CE Products registration in Germany/EU:
CE 产品申请注册的程序：

a. Party A shall submit the product registration application to Party B orally or in written.
甲方向乙方以口头或书面形式提出产品注册申请。

b. Party A shall submit to Party B the registration application form and technical files, of which the registration application form shall be provided by Party B and filled in by Party A. Party B may also provide technical file arrangements requirements for Party A’s reference when preparing files.
甲方向乙方提交产品注册申请表和技术文档，其中注册申请表由乙方提供、甲方填写；乙方还会提供技术文档的编排要求等供甲方准备文档时参考。

c. The technical files submitted by Party A shall be supplemented and corrected if there are any missing, incorrect contents or inconsistent formatting.甲方提交的技术文档，如有内容缺失、错误，编排格式有不符要求的，须进行文档的补充、纠正及修正。

d. Party A obtains product registration number.
甲方获得产品注册号码。

4. Technical files to submit for CE Products registration in Germany/EU:
CE 产品申请注册所需提交的文档：

a. Scan copy of CE product certificate (not required for self-declared products).
最新的 CE 产品证书扫描件（自我声明产品不需要）。

b. Soft copy of technical files in English with all files of Part A (especially the declaration of conformity, product description, labels and instructions) and risk management and clinic data of Part B—except the products which are clearly specified that do not require the clinic data according to MDD/IVDD and their annex.
CE 技术文件：英文、电子版本，文件的 A 部分都要（尤其是符合性声明，产品说明，标签，说明书等），B 部分的风险管理和临床数据—除非 MDD 等法规及附录明确不需要临床数据的产品可以不提供。

c. Photocopy or picture of CE products(not required for those already indicating in technical files).
CE 产品实样照片 / 图片（如果技术文件中有，则不必提供）。

d. Photocopy or picture of CE product labels exporting EU(not required for those already indicating in technical files).
CE 产品出口欧盟牌贴照片 / 图片（如果技术文件中有，则不必提供）。

e. Registration application form provided by Party B and filled in by Party A.
甲方填写的由乙方提供的注册申请表。

f. Other documents or files Competent Authorities requires.
主管当局要求提交的其他文档。

11. Update of the registration:
CE 已注册产品的更新：

If the CE certificate of the registered product or its declaration of conformity changes, the product registration update is required. Party A needs to submit to Party B the new CE certificate or the new declaration of conformity and a new registration application form, which enabling Party A to update the registration.
CE 已注册产品的 CE 证书或其符合性声明发生变更的，需要办理 CE 产品的注册更新。甲方只须向乙方提交产品新的 CE 证书、新的符合性声明以及注册申请表，即能办理产品的注册更新。

6. Withdraw and the Invalidation of the registration:
CE 已注册产品的撤销与失效：

a. The registration of the product will be withdrawn when its CE certificate is revoked, closed or withdrawn by notify body.
相关 CE 证书被发证机构撤销、关闭或收回时，产品注册撤销。

b. The registration of the product is withdrawn by EU Competent Authorities.
产品注册被主管当局撤销。

c. The registration of the product will be withdrawn when the MDD/IVDD agreement signed by Party A and Party B suspended.

甲乙双方签署的“MDD/IVDD AGREEMENT”中止时，产品注册撤销。

d. The registration of the product will become invalid if its CE certificate exceeds the validity.
CE 证书超过有效期的，产品注册失效。

e. The registration of the product will become invalid if the MDD/IVDD agreement signed by Party A and Party B fails to be renewed upon expiration.
甲乙双方签署的“MDD/IVDD AGREEMENT”到期未能续签的，产品注册失效。

f. The registration of the product will be withdrawn or become invalid if the other heavy conditions for withdraw or invalidation occur.
其他产品注册的撤销与失效的条件发生时，产品注册撤销或失效。

Everbiz GmbH
March 24, 2022　　2022 年 3 月 24 日

Annex 3 《Details of the Contacting persons of Party A and Party B》
附件三:《甲、乙双方第一通知人（联络人）以及联系方式》

Party A: JIANGSU ALPHAY MEDICAL DEVICE CO., LTD.
甲方： 江苏安惠医疗器械有限公司
Name: Qiang Wu
姓名：吴强
Mobile Phone 手机：
Tel (Office)办公电话：0513-85989732
E-mail 邮箱：sales@alphaymedical.com

Party B: Everbiz GmbH
乙方: Everbiz GmbH
Tel 电话: 089-54558164
Fax 传真: 089-54558333 E-mail 邮箱: info@everbiz.de
Address: Landsberger Str.155 80687 München Germany

Remark备注事项：
Either Party A or Party B shall notify the other party in written form or through E-mail on time once this party alters or adjusts or cancels certain information listed above. Any mistake arising from the failure to notify the other party shall be charged upon the party causing such mistake.
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，需书面或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一切责任。

Everbiz GmbH
March 24, 2022 2022 年 3 月 24 日