IVDD agreement

Device: SARS-CoV-2 IgG/IgM Rapid Test

Manufacturer Zhuhai Encode Medical Engineering Co., Ltd

Drafted by: Xiongwei Date: 2020.2.13

Reviewed by: Zengbingbing Date: 2020.2.16

Approved by: Sunyifeng Date: 2020.2.18

Document number : XGKTSJ-ODXYZL-01

MDD/IVDD AGREEMENT

E-20180125

Party A:
甲方：

Name: 公司名称（中英文）	珠海市银科医学工程股份有限公司 Zhuhai Encode Medical Engineering Co., Ltd		
Add: 注册地址(中英文)	珠海市金湾区红旗工业区虹晖二路 020 号 NO.020,Honghui 2nd RD Hongqi Industrial Zone,Jiwan District,Zhuhai,P.R China(519090)		
Production site :生产地址（中英文）	珠海市金湾区红旗工业区虹晖二路 020 号 NO.020,Honghui 2nd RD Hongqi Industrial Zone,Jiwan District,Zhuhai,P.R China(519090)		
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Party B:
乙方：

Name:	Prolinx GmbH
Add:	Brehmstr. 56, 40239, Duesseldorf, Germany
Tel:	0049 211 3105 4698
Fax:	0049 211 9367 2099
Contact Person:	Mr. Nianzhuang Liu
Dimdi Code:	DE/0000045300
Vat 税号:	DE815059178
Competent Authority Name:	Federal Institute for Drugs and Medical Devices (BfArM)
Competent Authority Code:	DE/CA20
E-mail:	med@eulinx.eu

Party A hereby appoints Party B as the authorized European Representative for their Medical Device with CE mark, the appointed product categories set out in Appendix A. And Party B accepts the appointment to be the authorized European Representative for Party A in the market of European Union（E.U.）, EEA and Switzerland, Turkey. 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、EEA、瑞士、和土耳其市场的 CE 医疗产品授权代表,委托的产品类别见附件一。双方签署下列协议：

Party A 甲方

1. Party A assures to provide the updated technical files of each product category with CE mark to Party B. Party A could firstly provide Part A of the technical file, and Part B would be submitted if required. If Party A cannot 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 vision), 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。甲方可以先提供 CE 技术文档的 PART A 部分，PART B 内容只有在需要时才提交。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档文件，文件可以是 PDF/WORD/JPG/TXT 格式的任何一种。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“附件二”。

2. If there are any changes of products and update of technical file, Party A shall notify Party B with change notification in electronic copy as soon as possible. Party A shall send relevant information to Party B's email listed as below within one week upon changing information: med@eulinx.eu.产品如有改变，技术文件如有更新，甲方需要在更新信息一周之内以电子邮件的形式，将相关信息发送到乙方以下电子邮箱：med@eulinx.eu。

3. If any accident/near accident of products(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 within boundary of E.U.,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 MDD 93/42/EEC (MDD products) ,IVDD 98/79/EC (IVDD 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.
   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.如果产品在欧盟境内及 EEA 和瑞士、土耳其之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（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。甲方应在《欧洲共同体理事会法令》按 MDD 93/42/EEC（MDD 产品）或 IVDD 98/79/EC（IVDD 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。
   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 be responsible for any business dispute related to their product problems, 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 pay all of the cost of the traffic and other allowance for PART B's employee or advisor in the china mainland for the need of investigation, analysis and disposal of the accident. Party B is entitled to require Party A to pay in advance. Before Party B receives such payment Party B is entitled to refuse to pay on behalf of Party A or take

relevant measures.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。在事故处理中，乙方需要在境外支付的相关费用，须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，乙方雇员或顾问在赴中国内地企业工作的食宿、交通等实际支出的费用，由甲方承担。乙方可以要求甲方支付相应的预付款，在该预付款到账到达乙方指定账户之前，乙方有权利拒绝代为支付或者采取相关措施。

5. Party A should keep the complete sales list of all of the products exporting to any area of E.U, EEA and Switzerland, Turkey (including the OEM products) by electrical documents in English at least 5 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., EEA and Switzerland, Turkey, Party A assures 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），在产品停产后至少五年期间，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 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 5th article on the above.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，按照上述第"5"条条款办理。

7. Party A should appoint two persons as the contact persons who connect with Party B and deal with the normal daily grind according to this agreement. Contact information of Party A should be written in Appendix C. 甲方需指定两人作为甲、乙双方的联络人，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。甲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 Switzerland, Turkey market without product registration to relevant competent authority of E.U. 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, EEA and Switzerland, Turkey 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登记备案就销售欧盟市场及 EEA 和瑞士、土耳其之必定带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入欧盟及 EEA 和瑞士、土耳其，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。

9. Party A shall notify Party B of the intentions of clinical investigation trials for MDD or AIMDD, and the intention of the performance evaluations for IVDD, which are to be performed in EU, EEA and Switzerland, 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 B is released by Party A of any liability relating to the medical devices manufactured by Party A. Party A will be fully responsible for the performance of its products and will hold Party B harmless against any liability claim arising from the use of the products manufactured

by Party A.甲方承诺，乙方不对甲方生产的医疗器械的索赔承担任何责任。甲方为其产品性能承担全部责任，并将确保乙方不会因为甲方生产的产品在使用过程中产生的任何责任索赔而承担损失。

11. Party A will inform Party B immediately if Party A adds, deletes or changes CE marked products. Party A need to sign an amendment agreement with Party B, otherwise the CE certificate may became invalid.甲方对带 CE 标识的产品进行增减和变更，须第一时间通知乙方，并且同乙方签订相关补充条款，否则将会导致 CE 证书失效。

12. Any liabilities for damage to any third party attributed to service stipulated herein provided by Party B, Party A shall bear all liabilities for damage and undertake to exempt any responsibilities of Party B to any third party. If it is required for Party B to employ any expert and counsel, especially to employ legal counsel to provide consultation and legal agency, Party A shall bear all relevant fees caused by the employment and pay such fees in advance upon request of Party B. 如果乙方因提供本协议规定的服务而产生对第三方的赔偿责任，甲方应当全权承担相关赔偿责任，并免除乙方对外的责任。如果乙方由此需要聘请专家和顾问，特别法律顾问提供咨询和法务代理，甲方应承担乙方因此而产生的相关合同费用，乙方有权要求甲方预付相关费用。

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 Appendix D). Party B shall review it within 10 working days, and submit it to competent authority of the country in which Party B is located (Germany) 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 German/EU relevant laws.甲方已取得 CE 证书或自我声明的产品，按欧盟相关规定(详见协议附件四)，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 个工作日内提交乙方所在国德国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，根据德国/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. 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 five 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五年后。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。

3. Upon receiving the CE technique files, Party B shall gave an electronic receipt to Party A within 3 working days. It's the evidence that Party B have received all the required files. 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 has the obligation to send them to competent authority if necessary. Part B should maintain and keep them secret.乙方收到甲方提供的 CE 技术文档等文件的 3 个工作日内，向甲方出具电子"回执"；该"回执"仅证明乙方收到甲方的文件，而不对文件的内容负责。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。

4. Party B shall keep following files of party A's products with CE mark at the disposal of the national authorities，at least for five years after leaving the last batch of products. Minimum documents are:
   a) Declaration of conformity,
   b) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
   c) Notified Body certification (where relevant),
   d) Post market surveillance process and data, vigilance reports and complaints, processes and data,
   e) Technical documentation relevant to market surveillance investigation being undertaken by the Member State,
   f) Relevant clinical data / notification,
   g) Details of any distributors / suppliers putting the CE marked devices on the market,
   h) 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五年。这些资料至少应包括：
   a) 符合性声明
   b) 标签、包装、说明书副本（所有上市国家要求的语言的版本）
   c) 公告机构证书（适用时）
   d) 与欧盟成员国上市监督调查有关的技术文件
   e) 相关的临床数据/通知
   f) 经销甲方 CE 标志医疗器械的经销商/供方细节
   g) 事故报告及采取的纠正措施
   h) 上市后监督过程和数据、警戒报告以及投诉、处理和数据

5. Part B must keep Part 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：

   5.1 Safeguard 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 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. "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于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。

5.2 Vigilance 警戒

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.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。

6. Party B shall notify promptly to Party A any information they could obtain about the Party A's products with CE marks in the territory of EU(including about the claims of customers and the competition companies 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信息（包括客户投诉和同类竞争企业）及时通知甲方。

7. If 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。

8. Party B shall appoint one person as the contact person whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of the contact person of Party B is written in the first page.乙方需指定一人，作为甲、乙双方的联络人，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。乙方联络人的联系方式记录在本协议的第一页。

9. 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 Switzerland, 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。

Party A & Party B 甲方及乙方

1. Written Form Clause 书面形式

Amendments to this Contract shall only be valid when given in writing. The requirement of form may only be waived in writing. Verbal collateral agreements or modifications are not valid.本协议的任何更改与补充均需以书面形式进行。这一规定同样适用于本条款（关于书面形式）的修改。口头协议和口头修改无效。

2. Severability clause 可分割性条款

If any provision of this agreement or a provision incorporated herein at a later date is or shall become invalid in whole or in part, or if this agreement or any modification thereof is found to have a gap, this shall not affect the validity of the remaining provisions. It is, however, the express intention of the parties to maintain the validity of the other provisions of the agreement under all circumstances. In place of any invalid provision or to fill a gap, a valid and enforceable provision shall be agreed which most closely corresponds legally and economically to that which the parties intended or would have intended within the meaning and purpose of the agreement and any later modifications, if they had considered this issue when concluding the agreements. If the invalidity of any provision is due to a measure of performance or time (time-limit or date) stated therein, a measure of performance which most closely corresponds to the original measure in a legally admissible way must be agreed for this provision.如若本协议中的条款或者其补充于现在或者将来无效，其他部分不受其影响，该规定同样也适用于协议内容缺失的情形。但协议双方明确表示，上述可分割性条款是为了确实保证合同其它部分不因合同部分无效而整体无效受到影响。就无效条款和缺失部分，协议双方应当在法律允许的范围内本着最接近原有合同目的，最能达到共同预期为标准，达成有效的补充规定，以替代该无效条款或者填补协议内容的缺失。

This agreement is subject to the requirement specified in the <EU 93/42/EEC Directive 1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the < MEDDEV 2.12-1 REV.8 January 2013>. Should there be any conflicts between this agreement and <EU 93/42/EEC Directive 1998>, <EU 2007/47/EEC Directive 2007>, <EU 98/79/EC Directive 2003> and the < MEDDEV 2.12-1 REV.8 January 2013> shall be followed as standards. 本协议受《欧共体关于医疗器械的 93/42/EEC 指令》，《欧共体关于医疗器械的 2007/47/EEC 指令》，《欧共体关于体外诊断医疗器械的 98/79/EC 指令》和《医疗器械警戒体系指南》约束。如本协议条款与《指令》或《指南》冲突，以《指令》和《指南》为准。

3. This Agreement is automatically terminated in any of the following circumstances. Party B shall not be responsible for any liability after the automatic termination of the agreement, Party A and Party B shall not cause compensation disputes. 有任何下列情况发生，本协议自动终止。乙方不承担协议自动终止后的任何责任，且甲乙双方不产生赔偿纠纷。

3.1) The Party A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notify body. 甲方的 CE 证书因事故被发证机构暂时吊销/关闭/收回的。

(When the above mentioned things happen, Party A is obligated to accomplish the following processes to avoid the further consequences: 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) Brief statement in written about the reasons why CE Certificate being withdrawn, being closed or being recalled by the notified body. 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) Written statement of non-sales if there are no products under the withdrawn, closed or recalled CE Certificate exporting to EU, EEA and Switzerland, Turkey market, or if there are products exporting, a written statement of sales would be required with the sales lists, risk assessments and the measures and timetable to cover the risk. 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。)

3.2) If Party A already receives CE certificate at time of signature of this contract, Party A appoints Party B as new EC Rep to replace existing EC Rep, in this case, this agreement expires automatically if Party A failed to provide Party B required technical files within 7 days after signature of this agreement by both parties.如果甲方已获得CE证书，委托乙方作为新的欧盟授权代表，替换之前的欧盟授权代表，甲方在甲乙双方签订本合同7日之内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。

3.3) Party A cannot 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. 如果甲方未获得过CE证书，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。

3.4) As a legal manufacturer, Party A has entered the EU, Switzerland, EEC or Turkey market without entrusting Party B to register the product at DIMDI. This agreement will automatically become invalid. 甲方作为生产商，在没有委托乙方进行产品DIMDI注册的情况下，其产品已经进入欧盟、瑞士、EEC或土耳其市场，本协议自动失效。

3.5) If Party A fails to update CE certificate and product sales record to Party B in time (January and July of each year), this agreement will automatically become invalid. 甲方没有及时（每年1月和7月）向乙方更新CE证书和产品销售记录的，本协议自动失效。

3.6) If the information and documents submitted by Party A to Party B are seriously inconsistent with the facts, this agreement will automatically become invalid. 甲方向乙方提交的材料与事实严重不符，本协议自动失效。

3.7) During the execution of the contract, this agreement will not be executed due to regulatory changes, and this agreement will automatically become invalid. 在合同执行期间，因法规变化导致本协议无法执行，本协议自动失效。

3.8) Party A doesn’t pay off the service fee according to this agreement and refuse to explain on the deadline, this agreement will automatically become invalid.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。本协议自动失效。

4. This agreement 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。

5. If Party A has not obtained CE Certification yet and Party A does not have the European Representative yet, the validation of this agreement is subject to the validation of upcoming CE Certificate. If Party A obtained already a valid CE Certification and would replace current European Representative, The validation of this agreement is five years after the signing.如果甲方还未获取 CE 证书，之前也没有欧盟授权代表，本协议有效期与即将获取的 CE 证书一致。如果甲方已经获取有效的 CE 证书或已经出具有效产品自我声明，希望更换现有欧盟授权代表至乙方，本协议自协议签订之日起五年有效。

Appendix:附：

1. Party B Label Sample 乙方欧代标识如下：

EC REP **Prolinx GmbH**
Brehmstr. 56, 40239 Duesseldorf
Germany

2. Appendix A <Production sites and product list>
Appendix B <Submitted the "technical documents directory" to the EU representative>
Appendix C <Emergency contact information>
Appendix D <Registration of CE product in Germany, the conditions, time, procedures and documents required to submit and updates, revocation and expiration of registered product>
Appendix E <Sales list management of products export to the EU market>
Appendix F <Charges of EU representatives and registration in Germany etc>
附件一《申请 CE 标识的产品列表》
附件二《提交欧盟代表的技术文档目录》
附件三《紧急联系人信息》
附件四《CE 产品德国申请注册的条件、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》
附件五《CE 产品出口欧盟市场销售清单管理方法》
附件六《欧盟代表及 CE 产品德国注册收费标准》
All these appendixes have the same effect as this Agreement 以上六个附件与本协议具有同等效力。

3. Except for this Agreement, neither Party A nor Party B shall be entitled to any other rights or obligations. 除本协议外，甲、乙双方不被赋予其他权利和义务。

4. This agreement reference, cited documents, laws and regulations 本协议参考、引用之文献、法规：
1) Council Directive 93/42/EEC 15.08.1998 and Council Directive 2007/47/EC 05.09.2007
2) Council Directive 98/79 EC 07.12.2003
3）GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM, MEDDEV 2.12-1 rev 8. January 2013
4) GUIDELINE FOR AUTHORIZED REPRESENTATIVES<MEDDEV 2.5/10> (January 2012)
1）《欧洲共同体理事会法令》（93/42/EEC）15.08.1998 以及《欧洲共同体理事会法令》

（2007/47/EC）05.09.2007
2）《体外诊断医疗器械》（98/79 EC）07.12.2003
3）《警戒系统指南》（医疗器械指令 2.12-1 REV.8 January 2013）
4）《欧盟授权代表指南》医疗器械指令 2.5/10 January 2012

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(甲方法人代表姓名、签字和盖章 / Signature)	(Prolinx 公司签名 / Signature)
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(日期 / Date)	(日期 / Date)

(Appendix A): 附件（一）:

For the following Product categories: 申请 CE 标识的产品列表如下，每类产品一行，更多产品请在下方自行添加:

No.	Product name	中文名称	产品分类（I,Is, Im, IIa,IIb,III 或 IVD 分类）
1	Chlamydia Trachomatics Antigen Test Cassette	衣原体抗原检测试剂盒	List B
2	Gonorrehea+Chlamydia Antigen Combo Test Cassette	衣原体+淋球菌抗原检测试剂盒	List B
3	Helicobacter Pylori (HP) Antigen Test Kit	幽门螺旋杆菌抗原检测试剂盒	Self-testing

(Appendix B)：附件（二）：

Submitted the "technical documents directory" to the EU representative: 提交欧盟代表的《技术文件目录》:

Part A A 部分

1) Name and address of manufacturer, 生产商名称、地址
2) Name and address of EU representative 欧盟代表名称、地址
3) Trade name of the device, device name, model, category and classification rules, certification approach 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 the production site 生产场地的名称、地址
5) Name and address of the notice organization 公告机构的名称、地址
6) Declaration of Conformity (signed version), CE and ISO13485 certification 符合性声明(签字版), CE 和 ISO13485 认证
7) Essential requirement checklist 基本要求检查表
8) A brief description of the product 产品的简要说明
9) Label, packaging and instructions for use 标签、包装、说明书
10) Regulatory requirements and standards used (harmonized standards) 使用的法规要求及标准（协调标准）
11) Related testing and testing of the introduction, such as clinical, electrical safety, mechanical safety, performance, etc., to list the relevant report or verification record number (reference B part), can be listed in the form of essential requirement checklist 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

12) Risk management documentation 风险管理文档
13) Compilation of clinical data, assessment of benefits and disadvantages 临床资料汇编，利与弊评估
14) Vigilance system 警戒系统
15) Test report (biocompatibility, physical properties, chemical properties, clinical, etc.) 检测报告(生物相容性、物理性能、化学性能、临床等)
16) production process description, production flow chart, special process description, key control points and so on 生产过程描述，生产流程图，特殊过程描述，关键控制点等

The A / B part of the document must, whenever necessary, provide to the EU representative with the latest version in writing or in electronic form; Part B documents are not limited to the items listed above. 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；B 部分文件不限于以上所列项目。

(Appendix C)：附件（三）：

Emergency contact information 甲方紧急联系人信息

联系人姓名，职务 Contact Name, Position	座机 Tel	手机 Mobile phone	邮箱 Email
崔淑珍,质量负责人 Shu zhen Cui,Quality Officer	+86-756-3983855	18575612269	happy.c2014@qq.com
孙宜峰,总经理 Yi Feng Sun,general manager	+86-756-3993000	18688166181	ceo@encode.com.cn

Note: Please provide two emergency contact containing the phone and the mailbox, so that we can deliver information from EU competent authority to your company in a timely manner when needed. If the emergency contact of Party A changes, please inform Party B immediately. If Party A fails to do so, then delay might happen, this consequence will be borne by the Party A. 注：甲方紧急联系人分别为总经理和质量部负责人，以便乙方在需要的时候，可以及时的将欧盟的相关信息传递给甲方。紧急联系人如果发生变化，请在第一时间知会，因甲方未及时通知而带来的拖延，责任由甲方承担。

(Appendix D)：附件（四）：

<Registration of CE product in Germany, the conditions, time, procedures and documents required to submit and updates, revocation and expiration of registered product>

《CE 产品德国申请注册的条件、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》

(1) Trigger to register CE product: CE 产品申请注册的条件：

1. Party A's products have obtained CE certificate, or made self-declaration in case of class I product. 甲方产品已经取得 CE 证书，或者一类产品已进行自我声明。
2. Party A's products are intended for the first time to bring into the EU, EEA, Switzerland, or the Turkish market. 甲方产品拟首次进入欧盟、EEA 或瑞士、土耳其市场销售。
3. Party A's products have not entered the EU, EEA or Switzerland, Turkey market, but would like to apply for "European free sales certificate" (also known as "Certificate of Marketability" or "Free Sale Certificate").甲方产品虽未进入欧盟、EEA 或瑞士、土耳其市场销售，但要求申请《欧洲自由销售合同》（又称“Certificate of Marketability”或“Free Sale Certificate”）的。

(2) Timeline for registration of CE product CE 产品申请注册的时间：

At least 30 days before the product intends to enter the EU, EEA or Switzerland, Turkey market.产品拟进入欧盟、EEA 或瑞士、土耳其市场前至少 30 天。

(3) Procedures of CE product registration CE 产品申请注册的程序

1. Party A to Party B in oral or written form of product registration application. 甲方向乙方以口头或书面形式提出产品注册申请。

2. Party A fill in and submit to Party B the product registration application form and technical documents, including the registration form provided by the Party B; Party B will also provide technical documentation requirements for the preparation of documents for reference. 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。

3. the technical documents submitted by Party A, if the content is missing, wrong, the layout format does not meet the requirements, they need to be amended and corrected. 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。

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

(4) Documents required for registration (English electronic version) CE 产品申请注册所需提交的文档（英文电子版本）

1. the latest CE product certificate scan (not relevant for self-declaration products); 最新的 CE 产品证书扫描件（自我声明产品不需要）;

2. CE technical documents: in English, electronic version, Part A of the document is the must (especially the declaration of conformity, product description, labeling, brochures, etc.). Part B of the risk management and clinical data - unless MDD and other regulations and the appendix clearly require, may not be submited; 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;

3. CE product photos / pictures (not relevent, if they are already included in the technical documents); CE 产品实样照片/图片（如果技术文件中有，则不必提供）;

4. CE products label photos (not relevent, if they are already included in the technical documents); 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）;

5. Application form filled out by Party A;甲方填写的由乙方提供的注册申请表;

6. Other documents requested by the German competent authorities. 德国主管当局要求提交的其他文档。

(5) Update of registered products: CE 已注册产品的更新：

If the CE certificate or declaration of conformity of the registered product has been changed, the update of product registration is required. Party A shall submit the new CE certificate, the new declaration of conformity and the registration application form to Party B for the update. 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) Withdrawn and invalidation of CE registered products CE 已注册产品的撤销与失效：

1. If the relevant CE certificate was revoked or withdrawn by the notified body, then the product registration will be withdrawn. 相关 CE 证书被发证机构撤销、关闭或收回时，产品注册撤销。

2. If product registration is revoke by the German authorities, then the product registration will be withdrawn. 产品注册被德国主管当局撤销。

3. If the signed the "MDD / IVDD AGREEMENT" become invalid, then the product registration will be withdrawn. 甲乙双方签署的“MDD/IVDD AGREEMENT”中止时，产品注册撤销。

4. If CE certificate expires, then the product registration will be invalid. CE 证书超过有效期的，产品注册失效。
5. If the signed "MDD / IVDD AGREEMENT" failed to renew, then the product registration will be invalid or withdrawn. 甲乙双方签署的“MDD/IVDD AGREEMENT“到期未能续签的，产品注册失效。
6. If any other revocation conditions occur, then the product registration will be invalid or withdrawn. 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。

Attachment: German competent authorities for medical device and product registration: 附：德国负责 CE 医疗器械产品登记等工作的主管当局网站：
1) www.bfarm.de (German Ministry of Health website 德国卫生部网址)
2) www.dimdi.de (German Institute of Medical Documentation and Information 德国 CE 标志医疗器械产品注册数据中心网址)

(Appendix E)：附件（五）：
<Sales list management of products export to the EU market>
《CE 产品出口欧盟市场销售清单管理方法》

(1) The basis for the development of this approach 本办法制定的依据
According to Guideline of Vigilance System 3.1 the European Authorized Representative: Upon receipt of the incident report, contact the manufacturer and the competent authority in time to communicate the customer's complaint and incident report to the manufacturer in a timely manner, The contents of the "MDD / IVDD AGREEMENT" signed by Party A and Party B are the basis and basis for the development of the management measures. 《警戒系统指南》中，有关欧盟代表职责的规定：“3.1 欧洲授权代表：收到事故报告后应及时与制造商及主管当局联系，及时把客户的投诉和事故报告传递给制造商，并负责保护产品销售记录。”的内容，以及甲、乙双方签定的《MDD/IVDD AGREEMENT》相关内容，是制定本管理办法的依据和基础。

(2)The method of management of this approach 本办法管理的方法
In addition to the relevant contents of the relevant sales list specified in Article 5 of Party A of the Agreement "MDD / IVDD AGREEMENT", Party A and Party B shall specify the following rules of operation 除了协议《MDD/IVDD AGREEMENT》中 PARTY A 部分第 5 条规定的有关销售清单的相关内容以外，甲、乙双方特约定下列操作细则，双方共同遵照执行：
1. initially scheduled for Party A to Party B on a regular basis every half a year, by e-mail submitted to the EU market sales list; specific time: July each year before the last working day, to submit this year from January 1 to June 31 Export list; the last working day in January each year before the date of July 1 to December 31 to submit the export list. 暂定为甲方每半年定期向乙方，用电子邮件方式提交出口欧盟市场的销售清单; 具体时间为：每年 7 月的最后一个工作日前，提交本年度 1 月 1 号至 6 月 31 号的出口清单; 每年 1 月的最后一个工作日前，提交上年度 7 月 1 号至 12 月 31 号的出口清单。
2. if Party A in the above specified period of time, no products exported to the EU market, but also need to submit a zero report to the B report. 如果甲方在上述规定的时间段里，没有任何产品出口欧盟市场的，也需要向乙方提交零申报报告。
3. Party A shall be responsible for the true and accurate of the declared data. If the above declaration contains omission, delay, concealment and other issues, Party A should be responsible for the resulting consequences. 甲方须对申报数据的真实、准确负责。如果上述申报发生漏报、迟报、瞒报等问题的，应有甲方负责由此而产生的后果。

4. Party B shall be responsible for the confidentiality and custody of Party A's contents and the obligation of timely delivery to the competent authorities of the European Union. 乙方对甲方的申报内容负有保密和保管的责任，以及向欧盟各主管当局如实、及时传递的义务。
5. the declaration, Party A to be signed to Party B; Party B received a declaration, must be issued to the Party A receipt. 上述申报，甲方需签章递交给乙方；乙方收到申报后，须向甲方出具回执。

(3) The format of the annex to the present method:本办法附件的格式:

Annex 1, Sales List Sample: (format for reference only)：
附件 1、销售清单样本：（格式仅供参考）：

Export Date	Commodity name	Batch no.	Production quantity	Export quantity	Import country	Export means	Remarks

Annex 2, zero declaration declaration format: (for reference only)
附件 2、零申报声明格式：（仅供参考）

《DECLARATION》

致：德国欧通商务咨询公司（乙方）：兹有珠海市银科医学股份有限公司（甲方），在本期：2018 年 1 月 1 号至 6 月 30 号，有关出口欧盟的销售清单内容，没有需要申报的数据，特此声明。

甲方代表签章
日期：

To: Prolinx GmbH (Party B)
We Surya Mas Daily Chemical(Tianjin) Co.,Ltd. (Party A) declare that there are no any export data in E.U. to submit during the period from Jan.01 to Jun.30,2018

Signature:
Date

(Appendix F)：附件（六）：
<Charges of EU representatives and registration in Germany etc>
《欧盟代表及 CE 产品德国注册收费标准》

EU Representation Agreement (MDD / IVDD AGREEMENT) Charges
欧盟代表协议 (MDD/IVDD AGREEMENT) 收费标准

1. When the number of products listed in the EU representative agreement does not exceed the baseline quantity (the number of production enterprises is 1-5 and the number of trade-oriented enterprises is 1-10), the agreement is charged at the following price: 当欧盟代表协议列明的产品数量不超过基准数量 (生产型企业的基准数量为 1-5 个，贸易型企业的基准数量为 1-10 个)时，协议按以下基准价格收费:
1) For the class I, I*, IIa and IVD in the General and Self-testing Products, the cost is 20,000 RMB / five years; 产品为 I、I*、IIa 类及 IVD 中 General 和 Self-testing 的，费用为人民币 20,000 元/五年；

2) For the class IIb and IVD List B Products, the cost is 25,000 RMB / five years; 产品为 IIb 类以及 IVD 中 List B 的，费用为人民币 25,000 元/五年；
3) For the class III and IVD List A, the cost shall to be agreed separately. 产品为 III 类以及 IVD 中 List A 的，费用另议。
4) When there are products corresponds to different classes, the higher cost applies.如同一份协议中产品对应不同类别时，按较高费用标准收费。

2. When the number of products listed in the EU representative agreement exceeds the number of benchmarks, the agreement shall be charged separately at the base price. In principle, if the number of products does not exceed 10, the standard fee shall be charged for each additional product with of RMB 3000. Above, the additional charges are negotiated.当欧盟代表协议列明的产品数量超过基准数量时，协议须在基准价格上另外收费，原则上产品数量超出基准数量 10 个以内的，按每个增加人民币 3,000 元标准收费，超出基准数量 10 个以上的，增加的收费标准另议。

3. During the validity period of the EU representative agreement, if Party A add the product or increase the self-declaration product to the corresponding CE certificate, Party A shall sign a supplementary agreement with Party B to expand the product. The validity of the Supplemental Agreement shall be consistent with the original agreement. The products on the Supplemental Agreement shall be charged at a rate of RMB 3000 per product.在欧盟代表协议有效期内，甲方需在对应的 CE 证书上增加产品或增加自我声明产品的,须同乙方签订欧盟代表的补充协议，将增加的产品扩充到原协议中。补充协议的有效期应同原协议一致。补充协议上的产品，按每个人民币 3,000 元标准收费。

4. Charges product registration in Germany　CE 产品德国注册收费标准
1) Registeration costs RMB 3,000 for each product. 甲方 CE 产品申请注册的，每个产品按人民币 3,000 元标准收费。

2) Update of existing registration costs RMB 2,000 for each product. 甲方 CE 产品已注册、申请注册更新的，每个产品按人民币 3,000 元标准收费。

5. Changes of company name， address， contact person or contact information of Party A costs RMB 3,000.甲方公司名称，地址，联系人或者联系人方式有变动的，每次按人民币 3,000 元标准收费。

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