EU Authorized Representative Agreement

NO. 20200309

Party A:
甲方： 纺源医疗用品集团有限公司

Name:	Textile Source Medical Supplies Group Co., Ltd.
Add:	No.12 Standard workshop, 69 Chang'gang Street, Guangxi ASEAN Economic and Technological Development Zone, China
Tel:	+86-0771-3901723
Fax:	+86-0771-3901723
Zip Code:	530105

Party B:

Name:	Caretechion GmbH
Add:	Niederrheinstr 71, 40474 Duesseldorf, Germany.
Tel:	+49 211 3003 6618
Fax:	+49 211 3003 6619
Contact Person	Mr. Jian Wang
Dimdi Code	DE/0000048026
E-mail:	info@caretechion.de

Party A hereby appoints Party B as the European Authorized Representative for their Medical Device with CE mark to provide authorized representation services as required per Directive 93/42/EEC and/or Directive 98/79/EC where applicable, the appointed product categories are set out in Appendix A.
甲方任命乙方为 CE 医疗器械的授权代表,提供所适用的医疗器械指令（Directive 93/42/EEC）和/或体外诊断医疗器械指令（Directive 98/79/EC）中所要求的授权代表服务，委托的产品类别名称、分类、型号清单及预期在欧盟境内销售的国家见附件一。

Hereafter when reference is made to the EU, this is meant to include the EEA, Switzerland and Turkey.
以下所提到的 EU，都指的是 EEA、瑞士和土耳其。

Party B shall provide the relevant service as stipulated herein as the authorized representative of Party A. However, Party B is not obliged to bear any product liabilities arising from the entry of Party A's medical products into the EU market, especially from its sale and use. Party A is the only responsible party. It is recommended that Party A purchases product liability insurance that is able to cover the volume and risk of products sold within the EU market.
乙方作为甲方的授权代表，提供本协议规定的相关服务。但乙方不承担因甲方医疗产品进入 EU 市场，特别是因销售和使用而产生相关的产品责任，对此甲方是唯一对外的责任人。
建议甲方购买产品责任保险，并使该保险足以涵盖其欧盟境内销售的产品量和风险性。

Party B accepts the appointment to be the authorized European Representative for Party A in EU. Both parties enter this agreement as below:
乙方接受甲方任命,为甲方在 EU 市场的 CE 医疗产品授权代表，双方签署下列协议：

A. Obligations and Liabilities
责任和义务

I. Party A
甲方

1. Party A shall ensure to provide the latest technical documentation and assessment report of the Notified Bodies (if any) of each product category with CE mark to Party B. The contents of the technical documentation shall comply with the requirements of the applicable European directives (eg Directive 93/42/EEC, Directive 98/79/EC, etc.), and the language of the technical documentation shall be the official language recognized in Europe. If Party A fails to provide Party B with the qualified CE technical documentation within 30 days after the certification is completed or before the self-declaration product is marked with CE, this Agreement shall automatically lapse. Party A shall bear all the consequences arising therefrom. Please refer to Appendix B for the detail requirements of the technical documentation.
甲方确保向乙方提供所有委托型号产品最新的技术文档和公告机构的评审报告（如有），技术文档的内容应符合所适用的欧洲法规（例如：Directive 93/42/EEC, Directive 98/79/EC 等）的要求，并且技术文档的语言应为欧洲认可的官方语言。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。
所提交文档内容的要求，详见本协议"附件二"。

   If necessary, the relevant technical data shall be provided to Party B within 2 working days when required by the European competent authorities for inspection.
在欧洲主管当局要求检查时，并在需要时，于 2 个工作日内向乙方提供相关技术数据。

2. If there are any changes of the products, update of the technical documentation, addition of product models or phase-out production, Party A shall inform Party B with the change notification in electronic copy, in particular, information is required for products that may affect registrations with competent authorities. Party A shall send relevant information to Party B's email within one week upon the changes: info@caretechion.de. The updated technical documentation should be provided in the meantime.
   If Party A fails to provide Party B with the information, this Agreement shall automatically lapse. Party A shall bear all the consequences arising therefrom.
产品如有改变，技术文档如有更新，或者新增产品型号，不再生产，需要告知乙方，尤其需要告知可能影响涉及主管当局注册的产品信息。甲方需要在更新信息产生后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：info@caretechion.de。更新的技术文档也应当同时提供。
如果甲方未将该信息及时告知乙方，本协议自动失效，甲方承担由此而引起的所有后果。

3. In the vigilance system, Party A is obliged to inform Party B to ensure that Party B is aware of the information about its products in the EU market. Party A shall immediately inform about the reportable events such as product incidents, recalls and the Field Safety Corrective Action (FSCA). Party B shall assess and decide whether to report to the competent authority
   If Party A fails to provide Party B with the information, this Agreement shall automatically lapse. Party A shall bear all the consequences arising therefrom.

在警戒系统中甲方对乙方有告知职责，确保乙方了解其产品在 EU 市场的信息，即时告知产品事故、召回等报告事件和市场安全纠正措施（FSCA），由乙方评估决定是否向主管当局报告。

如果甲方未将该信息及时告知乙方，本协议自动失效，甲方承担由此而引起的所有后果。

4. In the vigilance system, Party A shall provide Party B with the necessary information including information on the incident that has occurred, the investigation of the cause, the corrective actions taken, the implementation and closure of the incident, and deliver to Party B. Party A shall assist Party B in assessing the need for reporting, if necessary.
在警戒系统中甲方提供乙方需要的资料，包括收集已经发生的事故信息、原因调查、所采取的纠正措施及实施、关闭情况，传递给乙方。必要时，协助欧盟代表评估是否需要报告。

5. 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 China mainland during Party B's handling of the accident shall be borne by Party A. Party A shall pay all the cost of the traffic and other allowance for Party B's employee or consultant in China mainland for the need of investigation, analysis and handling of the accident. Party B is entitled to require Party A to pay in advance. Party B shall have the right to refuse payment on behalf of Party B or take relevant measures before the advance payment reaches the account designated by Party B.
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。

Party A shall keep the complete sales list of all of the products exporting to an E.U (including the OEM products) until at least 5 years (15 years for implanted products) after phase-out production. The sales list shall remain complete in English and electronic copy for the retrieval and inspection of EU. Party A shall be responsible for the accuracy and authenticity of the data provided. If Party A fails to meet with the information, this Agreement shall automatically lapse. Party A shall bear all the consequences arising therefrom.
甲方出口 EU 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（对于植入产品，停产后至少十五年），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 EU 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。如果甲方未满足该要求，本协议自动失效，甲方承担由此而引起的所有后果。

6. Party A shall inform Party B of the complaint record and results of the complaint handling on time. The storage, retrieval and inspection of all the records shall follow clause 5.
甲方针对客户/用户的事故的投诉、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 shall appoint two persons as the primary contacts who cooperate with Party B and deal with the daily work according to this agreement. The contact information of the

contacts shall be written in Appendix C. Party A shall notify Party B within two working days if there is any change in the contact person of Party A. Party A shall bear full responsibility for all the consequences arising from the failure to update the contact information promptly. The information delivered by Party B to the contact person of Party A shall be deemed to be delivered to Party A. The instructions given by the contact person of Party A shall be deemed as instructions given by Party A.
甲方需指定二人，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"。甲方联络人如有任何变更，甲方应于两个工作日内通知乙方；如果由于未能及时更新联络人信息所引起的一切后果，甲方应承担全部责任。乙方送达给甲方联络人的信息视作送达给甲方，甲方联络人给出的相关指示视作甲方给出的指示。

All notifications related to this Agreement shall be regarded as delivered at the following time points:
有关本合同的所有通知应视为已于下列时间送达：
(a) Upon arrival at the specified location if delivered by specified personnel;
如以专人递送，到达指定地址时；
(b) Upon successful printing of the confirmation notice by the sender's fax machine if delivered by fax;
如以传真方式，发件人的传真机打出成功传送的确认条时；
(c) The third day after sending out the notice if delivered by the express delivery;
如以快递方式，在发件后的第三日；

All above notices shall be delivered to the recipient's address listed as below, or to an address that either Party may appoint later.
上述通知应送至如下列所接收通知的地址或合同任一方于其后指定的地址。

8. Party A shall fully understand the risks arising from the sale of the EU market without registration or filing due to its delay, omission or concealment of the products. If the products are placed into EU market without registering and filing due to the cause of Party A, Party A shall bear the fines, warnings and even the consequences of suspending the CE product certificate and banning the products from entering the EU market.
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 EU 市场之必定带来的风险。如果由于甲方的原因，发生产品没有登记备案就进入 EU，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 inform Party B of the intentions of clinical investigation trials, which are to be performed in EU. *"Clinical trials may require additional contracts to clarify both liability and related costs.*
甲方应事先通知乙方在 EU 对医疗器械进行临床试验的计划。*临床试验可能需要在另外的合约以明确双方责任和相关费用。*

10. Party A shall promise that Party B will not take any responsibility for the claims manufactured by Party A on medical devices
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

11. 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。

12. Party B shall be solely responsible for the compensation and shall exempt Party B's external responsibilities if there are any liabilities to any third party attributed to service stipulated herein provided by Party B, If Party B thus needs to hire experts, consultants and special legal advisors to provide consulting and legal representation, Party A shall bear the relevant contract costs incurred by Party B and Party B shall have the right to require Party A to prepay the related expenses.
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。

II. Party B
乙方

1. Party B shall apply registration for the commissioned products (As listed in Annex A) with German competent authority in accordance with Article 14 of Directive 93/42/EEC, Article 10 of Directive 98/79/EC and MPG of German Medical Device Law. Party B shall confirm prior to registration that the technical documentation complies with the applicable EU regulatory requirements.
Party B shall perform the registrations in other countries if requested by Party A, which may result in additional costs.
Party B is responsible for the registration in Germany. The expenses shall be borne by party a. Before the registration is completed by Party B, the products commissioned by Party A shall not be exported to the territory of EU.
乙方将按照医疗器械指令（Directive 93/42/EEC）第 14 条 、体外诊断医疗器械指令（Directive 98/79/EC）第 10 条和德国医疗器械法 MPG 的要求，向德国主管部门注册甲方委托的产品（附件一中的产品），并在注册前确认技术文档符合欧盟适用法规要求。
如甲方提出要求，乙方将为其在需要额外注册的国家做额外注册，该注册可能产生额外费用。
乙方负责完成德国的注册，费用由甲方承担。在乙方完成注册前，甲方委托的产品不得出口到 EU 境内。

2. Party B shall reserve the technical documentation of each category of Party A's products with CE mark, and take up the responsibilities of keeping custody and confidentiality and submission upon the request of the competent authority. The technical documentation shall be reserved at least five years (fifteen years for implanted products) after the phase-out production. Once the technical documentation (including new version of the technical documentation which had already been filed) of each category of Party A's products with CE mark is requested by the competent authority, Party B shall submit within ten working days upon the receipt of relevant documents.
乙方应保留甲方每一型号获得 CE 标志产品的技术电子版文档，并负保管、保密和应要求提交当局的责任。该文档至少保存至最后一批产品停产五年后（植入产品保存至最后一批产品停产十五年后）。一旦欧盟主管当局需要获得 CE 标识产品的技术文档（含已备案的技术文档的新版本），乙方负责在收到相关材料后的 10 个工作日内递交欧盟主管当局。

3. Party B shall issue an electronic "receipt" to Party A within 3 working days after receiving the documents such as CE technical documentation provided by Party A, which only confirms the reception of the documents from Party A. Party B shall be responsible for submitting the sales list, complaint records and other documents provided by Party A for review by relevant EU institutions and keeping them custody and confidential.
Party B shall review and ensure the completeness and correctness of the technical documentation, after reception of the documents provided by Party A. Party B shall notify Party A in case of any non-conformity. Party A is responsible for the correction until it meets the requirements.
If Party A does not correct or the correction fails, Party B will not perform the registration (Part B Clause 1)
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，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。
乙方在收到甲方提供的 CE 技术文档后，组织评审，确定 CE 技术文件的正确性与完整性。评审如有不符合项，通知甲方，由甲方负责整改，直至符合要求。
如果甲方不予整改或整改不合格，乙方将不予注册（上述 Part B 条款 1 的规定）

4. In the vigilance system: Party B shall inform Party A of the information (including customer complaints) received by Party A about the commissioned products of Party A.
在警戒系统中：乙方应将收到的有关甲方委托产品的信息（包括客户投诉），告知甲方。

5. In the vigilance system, Party B shall communicate with the competent authorities on the protection of Party A's products in the EU market and the relevant measures in the event of an accident, and communicate to Party A immediately and accurately.
在警戒系统中，乙方能够与主管当局就 EU 市场上的甲方产品触及保障条款、事故时所采取的相关措施进行沟通，并立即、准确无误地传达给甲方。

6. In the vigilance system, Party B is responsible for assessing the incident and on-site safety as well as the necessity to report the corrective actions. Party B shall report the accident and FSCA to the competent authority within the prescribed time limit when the reporting criteria are met.
在警戒系统中，乙方负责评估事故和现场安全就纠正措施是否需要报告，在达到报告标准时将事故和 FSCA 在规定时限内报告主管当局。

7. Party B shall appoint two persons as the primary contacts who cooperate with Party A and deal with the daily work according to this agreement. Party B shall notify Party A within two working days if there is any change in the contact person of Party B. Party B shall bear full responsibility for all the consequences arising from the failure to update the contact information promptly. The contact information of the contacts shall be written in Appendix C.
乙方需指定二人，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。乙方联络人如有任何变更，乙方应于两个工作日内通知甲方；如果由于未能及时更新联络人信息所引起的一切后果，乙方应承担相应的责任。双方联络人的联系方式记录在本协议的"附件三"。

B. Service Fee
服务费用

Party A shall pay the service fees to Party B separately according to the agreement for the relevant service stipulated in Party A hereof provided by Party B.
就乙方提供本协议 A 部分规定的相关服务，甲方应当按照单独约定支付乙方服务费用。
Provided that Party A requires Party B to provide the service beyond the scope stipulated herein, both parties shall agree relevant fees separately in writing.
如果甲方需要乙方提供超出本协议规定之外的服务，甲乙双方应当对此另行书面约定相关费用。

C. Term and Termination of the Contract
合同的期限及合同的终止

1. Term of the Agreement
协议有效期
The validation of this agreement is subject to the validation of CE Certificate for the products under it, or is within five years after the signing of the agreement for the self-declaration products.
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。
2. During the execution of the agreement, this agreement is 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：
This agreement is terminated automatically when:
有任何下列情况发生，本协议自动终止：
2.1 The CE certificate is canceled by Party A, or the CE certificate is suspended or withdrawn by the notify body.
(In the event of any of the above facts, Party A shall take the initiative to cooperate with Party B to do the following after-work, otherwise, it will bear all the liabilities arising from inaction or misconduct:
i) Brief statement in writing about the reasons why CE Certificate being cancelled, suspended or withdrawn.
ii) Written confirmation of whether there are products exporting to EU market under the withdrawn CE Certificate. If no, a written statement is required; if yes, the sales list is required. The evaluation of risks arising, measures and timetable to solve the problem shall be provided in writing.)
甲方主动注销 CE 证书，或者 CE 证书被发证机构暂停/撤销的。
(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注销、暂停或撤销的原因。
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 EU 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。)

2.2 In the event that Party A fails to provide Party B with the qualified CE technical documentation within 30 days after the certificate is obtained or before the self-declaration product is marked with CE, the agreement is terminated automatically. Within 60 days from the date of termination, Party B can continue to perform the

duties of the EU Representative on behalf of Party A in order to facilitate Party A's employment of a new EU representative and change of CE certificate. Party B shall inform the Notified Bodies of the termination of the agreement timely.
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。

2.3 Party A doesn't pay off 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。

D. Miscellaneous
其他事项

1. Governing Law /Arbitration
适用法律/仲裁

All disputes between the parties arising in connection with this contract or the execution of this contract, including disputes concerning the validity of this contract and this arbitration clause shall be finally settled in accordance with the Arbitration Rules of the Chinese International Economic Commerce Arbitration commission (CIETAC) where the arbitration process is to execute of the CIETAC-location in Beijing without recourse to the ordinary courts of law. Upon request an incoming arbitral award can be declared enforceable by a national court The place of arbitration is Beijing, Republic of China. An appeal against the arbitral award is not possible. The arbitral award shall also decide about the costs of the proceedings including the costs of the arbitrators. The arbitral tribunal consists of three arbitrators. The substantive law of People's Republic of China is exclusively applicable to the dispute. The language of the arbitral proceedings is Chinese.
所有与本协议相关的或者就本协议有效性（包括本仲裁条款）产生的一切争议和纠纷应当根据位于北京的中国国际经济贸易仲裁委员会的仲裁规则予以解决，由此排除普通法院对之的管辖，仲裁裁决可通过向有管辖权的法院提出申请而得以强制执行。仲裁地为北京。该裁决为终局决定，不得上诉。仲裁裁决中应当对仲裁费用做出规定。仲裁庭将由三名仲裁员组成。争议适用中华人民共和国法律。仲裁语言为中文。

2. 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.
本意向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。

3. Contract Language
合同语言

This agreement exists in English and Chinese language. The English version is solely for

information purposes. The Parties agree that the Chinese version of this agreement alone shall prevail with legally binding effect.
本协议为中文和英文的对照版本 英文只是起翻译作用，本协议内容以中文为准

4. Severance clause
可分割性条款

In the event that the terms of this Agreement, or their supplements, are invalid now or in the future, the other parts are not affected, and the same also applies to the absence of the agreement. However, both parties to the agreement made it clear that the above severance clause is intended to ensure that the rest of the contract will not be affected as a whole by the ineffectiveness of the contract part. In case of invalid clause and missing part, both parties to the agreement shall, within the scope permitted by the law, reach the common expectation as the standard closest to the original contract and reach an effective supplementary provision to replace the invalid clause or fill in the missing part of the agreement.
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。

5. The rights and obligations as stipulated herein are limited to the products listed in one CE certificate obtained by Party A. If Party A obtains multiple CE certificates, Party A and Party B shall enter into an agreement separately according to the actual number of the certificates.
本协议所规定的权利和义务，仅限于甲方取得的一份 CE 证书列明的产品，若甲方取得多份 CE 证书的，甲、乙双方需按证书的实际份数分别签订协议。

6. Appendix A List of products applying for CE mark
附件一《申请 CE 标识的产品列表:》
Appendix B Table of contents for the Technical Documentation Submitted to European Representative
附件二《提交欧盟代表的技术文档目录》
Appendix C Contact Information
附件三《联系人信息》
Appendix D Conditions, Time, Procedures and Necessary Files of Application for Registration of CE Product in Germany and Update, Withdrawal and Invalidation of Registered Product
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》
Appendix E Management procedure of the sales list of CE products exporting to EU market
附件五《CE 产品出口欧盟市场销售清单管理方法》
Appendix F Payment Terms.
附件六《付款方式》
The above six appendix have the same effect as this agreement
以上六个附件与本协议具有同等效力。

7. In addition to this agreement, neither Party A nor Party B shall be given any other rights and obligations.
除本协议外，甲、乙双方不被赋予其他权利和义务。
8. Documents and regulations that are referenced in this agreement:
本协议参考、引用之文献、法规：
   1） European Union Medical Device Directive 93/42/EEC, 05.09.2007
   欧洲医疗器械指令 Directive 93/42/EEC, 05.09.2007
   2） Vigilance System Guidance (MDD 2.12-1 REV.8 January 2013)
   《警戒系统指南》《医疗器械指令 2.12-1 REV.8 January 2013》
   3） 《GUIDELINE FOR AUTHORIZED REPRESENTATIVES<MEDDEV 2.5/10>》(January 2012)
   4） 德国医疗器械法（The Act on Medical device）
   5） 德国医疗器械安全计划条例
   Verordnung über die Erfassung, Bewertung und Abwehr von Risiken bei Medizinprodukten (Medizinprodukte- Sicherheitsplanverordnung - MPSV)

Note: during the validity period of the agreement, any change involving the revision/update of the above regulations shall be carried out in accordance with the new version. Party A and Party B shall not sign a new agreement.
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、乙双方不在签订新的协议。

Part A: Textile Source Medical Supplies Group Co., Ltd.
甲方：纺源医疗用品集团有限公司

(法人代表签名 / Signature
公司盖章/ Stamp)

(日期 / Date) 2020.3.31

Party B: Caretechion GmbH
乙方：

Caretechion GmbH
Niederrheinstr. 71, 40474 Düsseldorf
Tel.:0211 300 366 18 Fax:0211 300 366 19
Email: info@caretechion.de
www.caretechion.de
Amtsgericht Düsseldorf HRB 82833
Ust.-ID :DE319481632

(签名 / Signature)

2020.04.02

(日期 / Date)

(Appendix A)

附件（一）：

List of products applying for CE mark:

申请 CE 标识的产品列表:

序号 No.	CE 证书号码（如适用） CE certification # （if applicable）	CE 证书有效期 (如适用) CE certification valid date (if applicable)	产品名称 Product name	型号 Model	UMDNS /EDMS	产品分类 Device Class (e.g.: I, Is, Im, IIa, IIb III, List A, List B, others)
1	Not Obtained	Not Obtained	Disposable Medical Mask	/	12447	I
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						

Table of contents for the Technical Documentation Submitted to European Representative
提交欧盟代表的《技术文件目录》

Part A

1) Name and address of manufacturer
生产商名称、地址
2) Name and address of European Representative
欧盟代表名称、地址
3) Trademark, name, model, classification and classification rules and certification method of product
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 site
生产场地的名称、地址
5) Name and address of Notified Body
公告机构的名称、地址
6) Declaration of Conformity (with signature), CE and ISO13485 certificates
符合性声明(签字版), CE 和 ISO13485 认证
7) Essential requirements checklist
基本要求检查表
8) Brief description of product
产品的简要说明
9) Languages used in label, instructions for use
标签语言、使用说明书
10) Regulatory requirements and standards applied (harmonized standard)
使用的法规要求及标准（协调标准）
11) Introduction of relevant inspection and test, such as clinical, electrical safety, mechanical safety, performance, etc., and list the numbers of relevant reports or validation records (refer to Part B) in the form of checklist of basic requirements if appropriate
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

12) Risk management file
风险管理文档
13) Compilation of clinical data and evaluation of risk/benefits.
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) Description of production process, production flowchart, description of special process, critical control point, etc.
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 provided in writing or in electronic form to the European representative at any time if necessary;
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；
Part B is not limited to the items listed above.
B 部分文件不限于以上所列项目。

Part A Contact Information
甲方联系人信息

Name 联系人姓名	Title 职务	Landline 座机	Mobile Phone 手机	Email 邮箱
邱文	主管	0771-3901723	18587696588	273426534@qq.com

Note: Please provide the information of two contacts, including landline, mobile phone and email, so that we can transfer the relevant information of the European Union to your company in a timely manner when needed.
注：请提供两名联系人信息包括座机、手机及邮箱，以便我们在需要的时候，可以及时的将欧盟的相关信息传递给贵司。

Part B Contact Information
乙方联系人信息

Name 联系人姓名	Title 职务	Landline 座机	Mobile Phone 手机	Email 邮箱
Jian Wang	Managing Director	0049 211 300 366 18	0049 01725666666	info@caretechion.de

Please inform of any change of contact information promptly.
联系人如果发生变化，请在第一时间知会我司。

Conditions, Time, Procedures and Necessary Files of Application for Registration of CE Product in Germany and Update, Withdrawal and Invalidation 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》

一、 Conditions of Application for Registration of CE Products
CE产品申请注册的条件：

Party A has obtained the CE certificate, or "Self Declaration" has been made for Class I products.
甲方产品已经取得 CE 证书，或者一类产品已进行自我声明。

二、CE product application registration time:
CE产品申请注册的时间：

The pre-market approval in EEA, Switzerland or Turkey takes at least 30 days.
产品拟进入 EEA 或瑞士、土耳其市场前至少 30 天。

三、Procedures of Application for Registration of CE Products
CE产品申请注册的程序：

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

2、Party A shall submit the application form for registration of product and the technical documentation to Party B. The application form for registration is provided by Party B and completed by Party A. Party B shall also provide the preparation requirements for technical files to Party A 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 files submitted by Party A shall be supplemented, corrected and amended if the contents are missing and incorrect, or if the format does not meet the requirements.
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 shall pay the registration fee to party B,Party A obtains the product registration number.
甲方支付乙方双方约定的注册费用，甲方获得产品注册号码。

四、Necessary Files of Application for Registration of CE Products (English electronic copy)
CE产品申请注册所需提交的文档（英文电子版本），

1、Scanning copy of the latest certificate of CE product (not required 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 documentation: English electronic copy, all items required in Part A (especially Declaration of Conformity, description of product, label, instructions for use, etc.), risk management, and clinical data required in Part B, which may not be provided if regulations like MDD/IVDD and appendices clearly indicate that the clinical data of the product are not required);
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，IVDD 等法规及附录明确不需

要临床数据的产品可以不提供);

3、 Sample photographs/pictures of CE marked products (not required if they are available in the technical documentation)
CE 产品实样照片/图片（如果技术文件中有，则不必提供）；

4、 Photographs/pictures of labels fixed on the CE marked products exporting to European Union (not required if they are available in the technical documentation)
CE 产品出口欧盟贴牌照片/图片（如果技术文件中有，则不必提供）；

5、Application form for registration (provided by Party B) completed by Party A.
甲方填写的由乙方提供的注册申请表。

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

五、Renewal registration of CE marked products
CE 已注册产品的更新：

If there are any changes of CE certificates or declaration of conformity of CE registered products, update of registration of CE products is required. Party A shall only submit new CE certificate, new declaration of conformity and application form for registration to Party B, so that the product can be registered and updated.
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。

六、Withdrawal and invalidation of registered product:
CE 已注册产品的撤销与失效：

1. When the relevant CE certificate is withdrawn, closed or recalled by the certification authority, registration of the product is 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. Registration of the product is withdrawn by the German authority.
产品注册被德国主管当局撤销。

3. When the EU Authorized Representative Agreement signed by the two parties is terminated, registration of the product is withdrawn.
甲乙双方签署的《EU Authorized Representative Agreement》中止时，产品注册撤销。

4. If the CE certificate exceeds the validity period, registration of the product is invalid.
CE 证书超过有效期的，产品注册失效。

5. When the EU Authorized Representative Agreement signed by the two parties is not renewed after expiration, registration of the product is invalid.
甲乙双方签署的《EU Authorized Representative Agreement》到期未能续签的，产品注册失效。

6. When other conditions related to withdrawal and invalidation of registration occur, registration of the product is withdrawn or invalid.
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。

Websites of competent authorities responsible for registration of CE medical device in Germany:
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)
www.bfarm.de(德国卫生部网址)

2） www.dimdi.de (Website of Data of Medical Device CE Registration in Germany)
www.dimdi.de(德国 CE 标志医疗器械产品注册数据中心网址)

Management procedure of the sales list of CE products exporting to EU market
《CE 产品出口欧盟市场销售清单管理方法》

一、Basis for the establishment of the procedure
本办法制定的依据：

The management procedure is established based on the provision on the responsibilities of the European Representative in *Vigilance System Guidance* "3.1 European Representative: after receiving the incident report, the European Representative shall contact the manufacturer and the competent authorities promptly, give the customer's complaint and incident report to the manufacturer, and be responsible for the protection of the product sales record" and the relevant contents of the EU Authorized Representative Agreement signed by the two parties.
《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《EU Authorized Representative Agreement》相关内容，是制定本管理办法的依据和基础。

二、Measures managed in the procedure
本办法管理的方法：

In addition to the relevant contents of the sales list as stipulated in Clause 6 of PARTY A in EU Authorized Representative Agreement, Party A and Party B specially agree on the following rules for operation which the two parties shall follow:
除了协议《EU Authorized Representative Agreement》中 PARTY A 部分第 6 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、 It is tentatively determined that Party A shall regularly submit the sales list of products exporting to the European market to Party B by email every six months. The specific time is as follows: the export list from January 1st to June 30th of the present year is submitted before the last working day of July; the export list from July 1st to December 31st of the previous year is submitted before the last working day of January.
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 30 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 there is no product exporting to the EU market within the prescribed period of time manufactured by Party A, a zero declaration report is also needed to be submitted to Party B.
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 authenticity and accuracy of the declaration data. If any omissions, delays, concealment and other issues occur in the declaration above, Party A shall be responsible for the consequences arising therefrom.
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 safekeeping of the contents of the declaration of Party A, as well as the timely information 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. As for the declaration above, Party A shall submit the file with the signature to Party B, and Party B shall issue a receipt to Party A after receiving it.
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。

三、Format of the appendix to the procedure:
本办法附件的格式：

Appendix 1. Template of Sales List (Format for reference only):
附件 1、销售清单样本：（格式仅供参考）：

序号 No.	产品名称 Product name	型号 Model	UMDNS/ EDMS	产品分类 Device Class	销售国家列表 Sales country list	出口日期 Export Date	批次号 Batch no. or SN	生产数量 Production quantity	出口数量 Export quantity	出口方式 Export means	备注 Remarks
1											
2											

附件 2、零申报声明格式：（仅供参考）
Appendix 2. Zero Declaration (Format for reference only):
《DECLARATION》
致：Caretechion GmbH（乙方）：兹有_____公司（甲方），在本期：__年 1 月 1 号至 6 月 30 号(或者是**年 7 月 1 号至 12 月 31 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: Caretechion GmbH (Party B)
We_____(Party A) declare that there are no any export data in E.U. to submit during the period from Jan.01 to Jun.30.20**(or from Jul.01 to Dec. 31, 20__).

Signature:
Date