Agreement on

EU Authorised Representative for Medical Devices

医疗器械欧盟授权代表协议

No. A0657LA001

This **Agreement on EU Authorised Representative for Medical Devices** (**"Agreement"**) is effective as of 09/07/2021 (**"Effective Date"**) and is by and between

本医疗器械欧盟授权代表协议（**"协议"**）由以下主体签署，并于 09/07/2021（**"生效日期"**）生效，

Party A/甲方

Name: Zhejiang Rongrong Hosiery Co., Ltd.

名称： 浙江荣荣袜业有限公司

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Party B/乙方

Name: MedPath GmbH

名称： 医通有限责任公司

Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

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E-mail/电邮: Info@medpath.pro

Web/网站: www.medpath.de

DIMDI No./DIMDI 代码: DE/0000047823

EUDAMED SRN/EUDAMED SRN 代码: DE-AR-000000087

Sales-Tax ID/销售税号: DE313841775

Responsible Competent Authority: BfArM, Germany
主管机构：联邦药品暨医疗器械署，德国
Code of Competent Authority/主管机构代码: DE/CA61
Party A and Party B are each a "Party" hereunder and, collectively, are the "Parties" hereunder.
甲方和乙方各方称为"一方"，合称为"双方"。

WHEREAS, Party A is a manufacturer of medical devices incorporated in [Yiwu, Zhejiang Province], China, and all the current and effective business license, permits and certificates were enclosed to this Agreement as Annex I.
鉴于，甲方是一家在中国[浙江省][义乌市]设立的医疗器械制造商，所有现行有效的营业执照、许可和资质附在本协议后作为附件一。

WHEREAS, Party A intends to sell Medical Devices in the market of European Union ("**EU**"), EEA, Switzerland, Turkey and North Ireland ("**Territory**") under the requirement of current effective Regulation (EU) 2017/745 MDR and/or Regulation (EU) 2017/746 IVDR ("**EU Regulations**").
鉴于，甲方有意根据现行有效的(EU) 2017/745 MDR 法规和/或(EU) 2017/746 IVDR 法规（"**欧盟法规**"）的要求在欧洲联盟（"**欧盟**"）、欧洲经济体、瑞士、土耳其以及北爱尔兰（"**区域**"）的市场销售医疗器械。

WHEREAS, Party A desires to appoint Party B as the EU authorized European Representative for the Medical Devices with CE mark in the Territory ("**EU Representative**") and pay for the services provided by Party B, and Party B intends to accept such appointment to be the EU Representative.
鉴于，甲方有意指定乙方作为甲方在区域内带有 CE 标志医疗器械的欧盟授权代表（"**欧盟代表**"）并向乙方支付服务费，同时，乙方有意接受上述指定担任欧盟代表。

NOW, THEREFORE, both Parties enter this agreement as follow:
据此，双方达成如下协议：

I. Definition of Medical Devices
医疗器械定义

1. The term "Medical Device" or "Medical Devices" as used herein shall mean the Party A's products identified on 'Annex II: List of Medical Devices' hereto ("**Medical Devices**"), which may be amended from time to time by written consent by both Parties.
本协议中使用的术语"医疗器械"的含义是《附件二：医疗器械产品清单》中所列举的甲方产品（"**医疗器械**"），且该产品清单经双方书面同意后可随时变更。

II. Appointment of EU Authorized Representative
欧盟授权代表的指定

1. Party A hereby appoints Party B, and Party B hereby accepts the appointment, as Party A's exclusive EU Representative for the Medical Devices in the Territory, subject to the terms and conditions of this Agreement. The Appointment of Party B shall be deemed as independent contractor relationship and Party B not as an employee, agent, subsidiary or corporate affiliate of Party A.
甲方特此指定乙方，且乙方特此接受上述指定作为甲方在区域内医疗器械独家欧盟代表。指定乙方作为欧盟代表应视为独立合同关系，乙方并非为甲方的员工、代理、分支机构或关联企业。

III. Term
合同期限

1. Subject to the other provisions, this Agreement will remain in force throughout entire lifetime of all devices as mentioned in Annex 2 of this agreement, which are put into use in the Territory. This agreement shall be updated at least once in every five (5) years along with the payment as described in Article V.1.1) of this agreement, in order to reflect any applicable revised regulatory requirements / guidelines.
受制于其他条款，本协议持续有效，直至区域内的医疗器械（如附录 2 描述）整个使用寿命完结。与第五条第 1.1)款描述的付费同时，本协议应当至少每 5 年更新一次。这个更新是为了体现最新的法规要求或者指南。

2. Notwithstanding the above, either party may terminate the Agreement with providing a written notice of cancelation at least ninety (90) days in advance.
尽管有前述规定，任何一方可提前九十(90)天书面告知对方以终止本协议。

3. During the implementation of the Agreement, this Agreement will be terminated automatically in the following circumstances:
在协议执行期间，如出现以下情形，本协议将自动终止：

1) When Party A's CE Certificate is withdrawn temporarily, recalled by the Notified Body, Party A is obligated to cooperate with Party B to accomplish the following processes within a reasonable time otherwise Party A shall be liable for the further consequences because of its omission or improper conducts:
当甲方的 CE 证书因故被公告机构临时吊销、收回时，甲方应在合理时间内主动配合乙方做好以下善后工作，否则甲方将承担由于不作为或者作为不当而产生的所有责任：

a. Prepare for a written statement about the reasons why CE Certificate is temporarily withdrawn or recalled by the Notified Body, and
准备书面陈述简要说明 CE 证书被公告机关临时吊销或收回的原因，以及

b. Prepare for a written statement that no Medical Devices under the withdrawn or recalled CE Certificate being exported to the Territory, or a sales list and written assessment regarding the risk as well as the measures and timetable to solve the problems if such Medical Devices have been exported to the Territory.
准备书面陈述确认被临时吊销或收回的 CE 证书所覆盖的医疗器械未出口至区域，或者若该医疗器械已经出口至区域，准备销售清单、以及书面评估可能产生的风险以及甲方解决问题的措施和时间表。

2) When Party A cannot provide the required Technical Documentation to Party B within thirty (30) days after the approval of CE certification, or before using CE mark on the respective Medical Devices, or before signing off the "EU Declaration of Conformity", Party A should be liable for the consequence occurred.
当甲方在 CE 证书获批后三十（30）天内，或者在相应医疗器械上使用 CE 之前，或者在签署“欧盟符合性声明”之前，仍未向乙方提供所要求的技术文档时，甲方应承担由此产生的责任。

3) When the Fees for being EU Representative is not paid to Party B on the due date according to this Agreement, and no explanation is provided by Party A.
当甲方未在协议规定的最后期限内向乙方付清其作为欧盟代表费用，而又不作解释时。

4) When Party A fails to perform the obligation set forth in Article IV.2.
当甲方未履行本协议第四条第二款所规定的义务时。

5) When Party A acts contrary to its obligations under MDR/IVDR, Party B will terminate this Agreement, and immediately inform the German competent authority and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of this agreement and the reasons therefor.
当甲方违反 MDR/IVDR 中规定的制造商的职责时，乙方将终止协议，并立刻通知德国主管当局以及相应产品的公告机构（如果有）终止协议，以及其原因。

4. In case of the cancelation of the Agreement provided in Article III.2, Party A shall look for a new EU Representative and inform Party B the information of new EU Representative within thirty (30) days upon receipt of the written notice of cancelation by either party. The ending date of Party B's services is the cancelation date indicated in the notice of cancelation, and the beginning date of new EU Representative's services is the second day of cancelation date indicated in the notice of cancelation. Before the beginning date of new EU Representative's services, all the documentations and information regarding the Medical Devices shall be

forwarded to new EU Representative, and Party A shall ensure the new EU Representative register itself as Party A's EU Representative with the competent authority. Party shall cooperate the new EU Representative for a smooth transfer. Both Party A and Party B shall communicate and coordinate with the new EU Representative with reasonable diligence. Agreement is terminated according to Article III.2, Party B will continuous to provide Services till the beginning date of new EU Representative's services for the purpose of compliance, and Party A shall pay for Party B's Services provided after the termination.

若本协议按照第三条第二款的约定终止时，甲方应在收到书面终止通知三十（30）天内寻找新的欧盟代表并通知乙方有关新欧盟代表的信息。乙方服务的终止时间为终止通知上写明的终止日期，新欧盟代表提供服务的起始时间为终止通知上写明的终止日期的次日。在新欧盟代表开始服务前，所有有关医疗器械的文件和信息应转交给新欧盟代表，并且甲方应确保新欧盟代表已在主管机构登记为甲方的欧盟代表。乙方应配合协助新欧盟代表的工作交接，甲乙双方都应尽合理的努力与新欧盟代表协商。双方同意，尽管本协议按照第三条第二款的约定而终止，为合规之目的，乙方仍将继续提供服务直至新欧盟代表服务起始之日，并且甲方应支付乙方在合同终止之后提供的服务。

In case of the termination of the Agreement provided in Article III.3, Party A shall look for a new EU Representative and inform Party B the information of new EU Representative without any delay. The beginning date of new EU Representative's services is when all the documentations and information regarding the Medical Devices shall be forwarded to new EU Representative and registration of new EU Representative with the competent authority is finished. Both Parties agrees that although the Agreement is terminated according to Article III.3, Party B will continuous to provide Services till the beginning date of new EU Representative's services for the purpose of compliance, and Party A shall pay for Party B's Services provided after the termination.

若本协议按照第三条第三款的约定终止时，甲方应及时寻找新的欧盟代表并通知乙方有关新欧盟代表的信息。新欧盟代表提供服务的起始时间为所有有关医疗器械的文件和信息已转交给新欧盟代表，并且新欧盟代表已完成欧盟代表的登记手续。双方同意，尽管本协议按照第三条第三款的约定

而终止，为合规之目的，乙方仍将继续提供服务直至新欧盟代表服务起始之日，并且甲方应支付乙方在合同终止之后提供的服务。

In either case, Party A shall coordinate with new EU Representative with reasonable diligence regarding the transfer of documentations and information of the Medical Devices.
在以上任一情形中，甲方都应尽合理努力与新欧盟代表协商进行医疗器械的文件和信息的转交事宜。

IV. Service Scope and Term of Medical Devices
医疗器械服务范围和期限

1. Party B shall provide Party A with the following services subject to the type of Medical Devices:
根据医疗器械的类型，乙方应向甲方提供如下服务：

   1) verify whether EU Declaration of Conformity and Technical Documentation have been drawn up and, whether an appropriate conformity assessment procedure has been carried out by Party A if applicable;
   核实甲方产品的欧盟符合性声明和技术文档是否已起草，以及甲方是否已开始执行适当的合格评定程序（如适用）；

   2) 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, issued in accordance with MDR Article 56 / IVDR Article 51, at the disposal of competent authorities for the period referred to in MDR Article 10(8) / IVDR Article 10(7).
   按照 MDR 第十条第八款/ IVDR 第十条第七款中规定的期限，保留技术文件副本，欧盟符合性声明以及（如果适用）根据 MDR 第 56 条/ IVDR 第 51 条签发的相关证书的副本，随时提供给主管当局。

   3) comply with the registration obligations laid down in MDR Article 31 / IVDR Article 28 and verify that the manufacturer has complied with the registration obligations laid down in MDR Articles 27 and 29 /

IVDR Article 26;
履行 MDR 第三十一条/IVDR 第二十八条中注册的义务，并且核实甲方履行了 MDR 第二十七条和第二十九条/IVDR 第二十六条中注册的义务；

4) in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of Medical Devices, in an official Union language determined by the Member State concerned.;
用主管当局确定的语言，回复主管机关的请求以便主管机关有所有必要信息和文件证明医疗器械符合相关标准；

5) forward to Party A any request by a competent authority of the Member State in which Party B has its registered place of business, or access to Medical Devices; and verify that the competent authority receives the samples or is given access to the Medical Devices;
向甲方传达乙方商业登记地成员国主管机关有关医疗器械的任何请求，或获得医疗器械；并核实主管机关是否已收到医疗器械样品或被允许获得医疗器械样品；

6) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by Medical Devices; and
与主管机关合作采取预防或纠正措施消除，或在不可能消除危险时，减少医疗器械带来的危险；以及

7) immediately inform Party A about complaints and reports from healthcare professionals, patients and users about suspected incidents related to Medical Devices for which they have been designated.
立即通知甲方来自医疗专业人员、病患和用户有关其使用的医疗器械疑似事故的投诉和报告。

2. To perform the above services by Party B, Party A shall
为使乙方履行上述服务，甲方应

1) Provide Party B with the list of Medical Devices and any necessary information required for registration at least thirty (30) days before export to the Territory;
至少在医疗器械出口至区域内前三十（30）天向乙方提供医疗器械清单以及登记所需的所有必要信息；

2) inform Party B any amendments, updates, changes of Party A and/or Medical Devices within one (1) business days upon it occurs;
在甲方和/或医疗器械发生任何变更、更新之日起一（1）个工作日内通知乙方该等变更和更新；

3) ensure that any information and documents provided to Party B regarding Party A and the respective Medical Device are true and accurate; and
确保向乙方提供的关于甲方和各个医疗器械的所有信息和文件都真实和准确；以及

4) actively cooperate with Party B on any actions and investigation required by the competent authority.
积极配合乙方进行主管机关要求的任何措施和调查。

Provided Party A fails to perform the above obligations in Article IV, Party A shall bear any damages, losses, and fines incurred to Party B.
若甲方未能履行第四条约定的义务，甲方应承担由此给乙方带来的任何损失和罚款。

3. Unless otherwise provided in this Agreement, the service term for each Medical Device is starting from first day on which the name of Medical Device was listed on 'Annex II: List of Medical Devices' and remain effective till the termination or cancellation of this Agreement (**"Service Term of Medical Devices"**).
除非本协议另有约定，每个医疗器械的服务期自该医疗器械名称列入《附件二：医疗器械清单》之日开始持续有效，直至本协议终止或取消。

V. Calculation and Payment of Fees of EU Authorized Representative

欧盟授权代表费用的计算与支付

1. Party A agrees on the paying for fees as follows ("**Fees**"):
甲方同意支付以下费用（"费用"）：

   1) service fee for retaining Party B as the EU Authorized Representative is charged every five (5) years starting from the Effective Date, which is due at least thirty (30) days before the last day of every five (5) years' payment cycle;
   聘用乙方作为欧盟授权代表的服务费用，自本协议生效日期起每五（5）年收取一次，甲方应在每五（5）年付款周期到期日前至少三十（30）天付款；

   2) handing fees for one-time add, change and/or updates of 'Annex II: List of Medical Devices'.
   一次性添加、修改和/或更新《附件二：医疗器械清单》的手续费。

   3) If Party A uses the service provided Party B as described in Article VI.6 and VI.9 of this agreement on a voluntary basis, Party A shall pay the service fee to Party B according to current hourly rate of audit of MHS/TUV SUD PS GmbH. This rate is published by MHS/TUV SUD PS GmbH on its website.
   基于自愿基础，如果甲方使用乙方在此协议第六条第六款和第九款中提到的服务，应该按照当时德国 TUV 南德医疗部审核费用的小时费率付款。此费率可以公开地在德国 TUV 南德医疗部的网站上查询。

VI. Rights and Responsibilities of Party A
甲方的权利和义务

1. Party A represents and warrants to Party B that the Medical Devices are in fully compliance with applicable regulations and rules in the Territory, are free from defects in materials and workmanship, and will conform with all claims and specification in the respective EU Technical Documentations.
甲方向乙方陈述并保证，医疗器械完全符合区域内相关的法律法规要求，

材料和工艺均无缺陷，并符合每个 EU 技术文件中的声明以及技术指标的要求。

2. For the purpose of registration in the Territory, Party A shall provide Party B with current-valid EU Declaration of Conformity, Technical Documentation according to the requirements in MDR/IVDR, and CE certificate (if applicable) of respective Medical Devices within thirty (30) days before the registration. EU Declaration of Conformity and Technical Documentation shall satisfy the requirements of EU Regulations.
为在区域内登记之目的，甲方应在登记前三十（30）日内向乙方提供每个医疗器械所对应的当前有效的欧盟符合性声明、符合 MDR/IVDR 要求的技术文档、以及 CE 证书（如适用）。欧盟符合性声明和技术文档应符合欧盟法规的要求。

3. If there are any substantial changes of Party A and/or the registered Medical Devices, including but not limited to any substantial information updates on EU Declaration of Conformity and CE certificate, contact information updates of the general part of the Technical Documentations, change of name and address of Party A, additional variation/models of Medical Devices, Party A shall notify Party B in written within one (1) business day upon such change occurs.
若甲方或已登记的医疗器械出现任何重大变更，包括但不限于欧盟符合性声明和 CE 证书中的重要信息发生变更、技术文档中的联络方式变更、甲方名称和地址变更、医疗器械的补充型号等，甲方应在出现变更起一（1）个工作日内书面告知乙方。

4. If any serious incidents, field safety corrective actions, trends as specified in Article 88 of Regulation (EU) 2017/745 MDR and/or Article 83 of Regulation (EU) 2017/746 IVDR, register of complaints of non-conforming devices and of recalls and withdrawals, complaints or reports from healthcare professionals, patients or users about suspected incidents received by importers and distributors regarding Medical Devices which have placed on the market in the Territory, Party A shall investigate the reason in time, and complete the vigilance report. Party A shall inform

Party B the above events in written in one (1) business day, and submit the investigation result and the vigilance report to the relevant competent authority according to the EU Regulations, and other applicable guidelines.
若投放入区域内市场的医疗器械出现任何严重事故、现场安全纠正措施、欧盟 2017/745 MDR 法规第八十八条和/或欧盟 2017/746 IVDR 法规第八十三条规定的趋势、不合规器械和产品召回的投诉登记、医疗专业人士、病患或用户从进口商和分销商获得就疑似事故的投诉或报告，甲方应在合理时间内调查，完成警戒系统报告。甲方应在一（1）个工作日内书面通知乙方上述情形，并根据欧盟法规或其他适当规定向主管机关提交调查结果和警戒报告。

If any field safety corrective action of Medical Devices occurs beyond the Territory, Party A shall report it to the relevant competent authority and notify Party B in written in one (1) business day.
若任何有关医疗器械的现场安全纠正措施出现在区域外，甲方应向主管机关报告此事，并在一（1）个工作日内书面通知乙方。

5. Party A shall preserve and make available any of the records mentioned in Article VI.4 in the agreement.
甲方应保存并提供此协议第六条第四款所涉及的所有报告。

6. Party A may, before any documents was submitted to the respective competent authority, voluntarily request Party B to review the appropriateness of the documents. This is a chargeable service provided by Party B. Party B shall review these documents based on his/her best expertise, however, is not responsible for the output of the assessment from the respective competent authority. Party A takes overall responsibility of the information and documents provided to the competent authority.
在任何文件被提交给主管当局之前，甲方可以在自愿的基础上，请求乙方检查文件的合适性。这是乙方提供的收费的附加服务。乙方将用它拥有的最高专业度来检查这些文件的合适性，但是不对后面主管当局检查的结果负责。甲方对于提供给主管当局的任何信息以及文件负全责。

7. Party A fully understands and undertakes that Party B is merely a representative in the Territory mandatorily required by EU Regulations, not an importer, distributor, seller of the Medical Devices. Party A further undertakes that only Party A is liable for any product liability of Medical Devices. Party A shall compensate Party B with the corresponding amount, in case Party B needs to bear liability based on European legal verdict.
甲方完全理解并同意，乙方仅仅是根据欧盟法规强制要求的在区域内的代表，乙方不是医疗器械的进口商、分销商、销售方。甲方进一步同意，仅由甲方承担医疗器械的所有产品责任。如果乙方由于欧盟法律裁决，而必须承担产品责任，则甲方向乙方赔偿相应的金额。

8. Party A shall purchase product liability insurance for the sales in EU. The coverage of the insurance shall be appropriate to match the product's risks and the sales volume/amount in the EU. The insurance shall cover product liability cases related to the product and shall cover the period as long as the validity period of this agreement.
甲方应为其产品在欧盟地区的销售，购买产品责任保险。保险的覆盖范围与产品自身的风险以及欧盟的销售数量/金额相匹配。该保险应涵盖与产品有关的产品责任案件，并且应在本协议有效期间内持续有效。

9. In response to the request from the competent authority, Party A shall
为回应主管机关的请求，甲方应

   1) provide that competent authority with all the information and documentation necessary to demonstrate the conformity of the Medical Devices, in an official Union language determined by the Member State concerned, without any delay;
   及时向主管机关提供其所在成员国指定的官方语言书就的所有信息和文件用以证明医疗器械符合要求；

   2) cooperate with the competent authority on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by the Medical Devices; and
   与主管机关配合采取防御或纠正措施消除、或减小医疗器械带来的危险

（若不可能消除危险时）；以及

3) be responsible for any disputes related to product liability of Medical Devices, such as any claims for compensation concerning product quality that arise after sale.
对与医疗器械产品责任相关的所有争议承担责任，如售后的产品质量问题导致的所有赔偿请求等。

Party B may assist Party A to handle the above issues in accordance with the written authorization of Party A. All the expenses occurred during Party B's handling of such issues shall be borne by Party A. Party A should pay all of the costs of accommodations, traffic and other allowance for Party B's employee or advisor for the need of investigation, analysis and disposal of the dispute.
乙方可根据甲方书面授权协助甲方处理上述事务。乙方在处理事务过程中产生的所有费用均由甲方承担。为调查、分析和处理纠纷之需，乙方应承担所有乙方雇员或顾问的食宿、交通等实际支出的费用。

10. Party A should keep the complete sales list of all Medical Devices exporting to the Territory including any OEM products ("**Sales List of Medical Devices**") by electrical documents in English for at least ten (10) years after the last device has been placed on the market, or in the case of implantable devices, fifteen (15) yeas the last device has been placed on the market in the Territory in order to be provided to Party B for the purpose to be forwarded to or inspected by the competent authority.
为向主管机关提供或接受主管机关检查之目的，甲方应使用英文电子文档保存所有进口到区域内医疗器械产品包括代加工产品的完整销售清单（"**医疗器械销售清单**"）并提供给乙方，一般医疗器械销售清单的保存期限应自最后一个产品投入市场后至少十（10）年，植入式医疗器械销售清单的保存期限应自最后一个产品投入市场后至少十五（15）年。

Party A should provide Party B with the Sales List of Medical Devices of last calendar year through email before January 15 of Chinese Luna Year calendar. Such duty of Party A will not be waived even though there are no sales in one calendar year, and Party A shall provide declaration of no

sales to Party B.
甲方应在中国农历一月十五日之前使用电子邮件向乙方提供上一年度医疗器械销售清单。该等甲方义务并不因某一年度无销售记录而豁免，甲方仍应向乙方提供零销售申报。

Party A shall ensure the accuracy and validity of the above-mentioned data and be liable for fines, damages and losses incurred by any omission, delay or conceal of the above submission.
甲方应确保上述数据的准确性和真实性，并承担因疏忽、延迟、隐瞒上述申报而产生的罚款和损失。

11. Before importing Medical Devices in the Territory, Party A shall finish registration of the respective Medical Devices according to the EU Regulations, and ensure that the label of Medical Devices bears the name and registered place of Party B as the EU Representative. Party A shall fully realize and understand the risk and consequence of importing Medical Devices in the Territory without the registration. If any delay, omission or cancelation of registration was caused by Party A, Party A shall be responsible for any consequence, such as warnings, penalties, cancelation of CE certificate, and prohibition of distribution of Medical Devices in the Territory. Party A shall also compensate Party B's any damages or losses incurred as being EU Representative.
在医疗器械进口至区域内之前，甲方应按照欧盟法规的要求完成各个医疗器械的登记事宜，并确保医疗器械的产品标签中注明作为欧盟代表的乙方的名称和注册地址。甲方充分理解，将未登记的医疗器械进口至区域内的风险和后果。若因甲方原因的延迟、疏忽或隐瞒的情形，甲方应承担所有责任，包括警告、罚款、吊销 CE 证书、以及禁止医疗在区域内销售。此外，甲方应向乙方赔偿其作为甲方欧盟代表所遭受的所有损失。

12. Party A agrees that all the obligations regarding importers and distributors in this Agreement shall be incorporated to the agreement with importers and distributors, otherwise any fines, damages or losses incurred to Party B shall be bored by Party A.

甲方同意，本协议中涉及到进口商和分销商的所有义务条款应放入其与进口商和分销商的协议中，否则甲方承担乙方由此受到的任何罚款和损失。

VII. Rights and Responsibilities of Party B
乙方的权利和义务

1. As for the registration for Medical Devices with the competent authority, Party B shall review the required documents provided by Party A, and verify the information with Party A if there is any questions, within ten (10) business days upon the receipt of such documents, and file the applications with the competent authority of the country in which Party B is located within ten (10) business days upon the finalization of the required documents.
为在主管机构登记医疗器械，乙方应在收到甲方提供的必要文件之日起十（10）个工作日内审核其内容并与甲方核实相关问题，并且在必要文件已定稿后十（10）个工作日内向乙方所在国主管机构提交申请登记的文件。

2. Party B shall reserve the following electronic files of Medical Devices for ten (10) years, or fifteen (15) years in the case of implantable device, upon the last Medical Device has been placed on the market in the Territory, and be responsible for keeping confidentiality and submitting upon the request by competent authority. The files include:
乙方应自最后一个医疗器械投入区域内市场时起保存以下医疗器械的电子文档十（10）年，若是植入式器械，应保存十五（15）年。该文档包括：

   1) EU Declaration of Conformity;
   欧盟符合性声明；

   2) Technical Documentations;
   技术文档；

   3) CE Certificate;
   CE 证书；

4) Sales List of Medical Devices, including the details of any importers and distributors;
医疗器械销售清单，包括进口商和分销商的信息；

5) copy of the label, packaging and instructions for use (in all languages requested by the countries where Medical Devices are marketed) ;
使用医疗器械投放市场所在国所要求的语言书写的标签、包装和使用说明书的副本；

6) serious incident reports and field safety corrective actions taken in the Territory;
发生在区域内的严重事故的报告和现场安全纠正措施；

7) field safety corrective actions taken beyond the Territory;
发生在区域以外的现场安全纠正措施；

8) trends as specified in Article 88 of Regulation (EU) 2017/745 MDR and/or Article 83 of Regulation (EU) 2017/746 IVDR; and
欧盟 2017/745 MDR 法规第八十八条和/或欧盟 2017/746 IVDR 法规第八十三条规定的动态；以及

9) Any amendment and updates of the above documents.
上述文件的所有修订和更新。

3. Party B shall keep Party A informed in all matters that may be associated to the Medical Devices placed on the market in the Territory. At the minimum, the exchange of information concerning following shall be covered:
乙方应随时通知甲方所有关于投入到区域内市场中的医疗器械的事宜，应至少包括：

1) If the competent authority contacts Party B about its interim measures to withdraw Party A's Medical Devices from the market, or prohibit or restrict their being placed on the market or put into service, Party B should communicate such measures to Party A without any delay.
若主管机构就有关对甲方医疗器械采取撤出市场、禁止或限制上市或投入使用的临时措施而联系乙方，乙方应立即将相关措施与甲方沟通。

2) 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 its EU Representative. If the competent authority contacts Party B, Party B should communicate such information to Party A without any delay.
当欧盟委员会认为保障条款下的国家措施不合理时，欧盟应立即通知采取措施的成员国和制造商或其欧盟代表。若主管机关就此事联系乙方，乙方应立即与甲方沟通。

3) If the competent authority contacts Party B about its assessment outcome of accidents of Party A's Medical Devices, Party B should communicate such information to Party A without any delay.
若主管机构通知乙方关于甲方产品事故的评估决定，乙方应立即就此事联系甲方并且使甲方知晓主管机构的决定。

4. Party B shall notify any customers' claims to Party A regarding the Medical Devices within boundary of the Territory without any delay.
乙方应及时通知甲方所有关于区域内医疗器械的客户投诉。

5. If there are any substantial changes of Party B, including but not limited to the relocation to a new address and changing name, Party B shall notify Party A with change notification in written within ten (10) business days upon such change occurs.
若乙方有重大变更，包括但不限于变更地址或者名称时，乙方应自该等变更发生之日起十（10）个工作日内书面通知甲方。

VIII. General terms for Party A and Party B
甲方及乙方共同条款

1 Each party should appoint one or two persons as the primary contact who connect with the other party and deal with the normal daily grind according to this Agreement. Information of both Parties' contact should be written in 'Annex 3: Information of Primary Contact'.

每方应指定一至二人作为第一联络人，负责与对方沟通、共同协调处理本协议条款约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：联络人信息》。

Any changes and updates of the above information shall be informed to other party in writing without any reasonable delay. If one party could not receive any information from other party due to failure of informing such changes and updates, the non-fault party shall be responsible for any damages or loses incurred.
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。

2. Obligations and rights described in this Agreement between Party A and Party B are only valid within the scope of Medical Devices listed in Annex 2.
本协议所规定的双方权利和义务，仅限于附件二中列明的产品范围。

3. Obligations and rights of both Parties are limited as described in this Agreement unless otherwise stipulated by EU Regulations regarding the Medical Devices in the Territory. The validity and construction of both Party's obligations and rights are governed by this Agreement and EU Regulations.
除欧盟法规对区域内的医疗器械另有规定外，本协议所约定的双方权利义务按照本协议约定执行，甲、乙双方不被赋予其他权利和义务。双方权利和义务的有效性和解释受制于本协议和欧盟法规。

4. Party shall keep any information of Party B confidential, according to applicable Chinese laws. Party B shall keep any information of Party A confidential, according to applicable Chinese and European law. Unless with written consent, or required by governmental authorities, both Parties shall keep the information from each other confidential.
甲方应当按照中国相应法规要求，对于乙方信息进行保密。乙方应当按照中国和欧盟相应法规要求，对甲方信息进行保密。除非有对方书面许可，或者是政府部门要求信息时，否则，甲乙双方都不应当对外披露任何对方信息。

5. The validity, construction and performance of this Agreement shall be governed by and interpreted in accordance with the applicable laws of the P.R. China.
本协议的有效性、解释和履行受中国法管辖并根据中国法解释。

6. All disputes arising from the execution of, or in connection with, this Agreement shall be settled amicably through friendly negotiation. In case no settlement can be reached through consultations, the disputes in question shall be submitted to China International Economic and Trade Arbitration Commission Shanghai Branch for arbitration in accordance with the arbitration rules and the procedure for the said commission. The arbitration shall take place in Shanghai, China. The arbitration award shall be final and binding on the Parties thereto. The cost of arbitration shall be borne by the losing party.
凡因执行本协议所发生的或与本协议有关的任何纠纷，双方应通过友好协议解决。若未能通过协商解决的争议应提交中国国际经济贸易仲裁委员会上海仲裁分会，根据该仲裁规则进行仲裁。仲裁地点为中国上海。仲裁裁决为终局，对双方均有约束力。仲裁费用由败方承担。

7. The Agreement was made in English and Chinese, and Chinese version of this Agreement shall prevail if any discrepancy.
本协议以中英文书就，若两种版本之间出现分歧，则以中文版本为准。

Annexes:
附件：

- **Annex 1: Business License, Permits and Certificates of Party A**
  附件一：甲方营业执照、许可证、资质证书
- **Annex 2: List of Medical Devices**
  附件二：医疗器械产品清单
- **Annex 3: Information of Primary Contact**
  附件三：联络人信息

Party A 甲方	**Zhejiang Rongrong Hosiery Co., Ltd.** **浙江荣荣袜业有限公司**	**Party B** 乙方	**MedPath GmbH** 医通有限责任公司
Signature/签字		Signature/签字	
Stamp/盖章		Stamp/盖章	MedPath GmbH Mies-van-der-Rohe-Strasse 8 · D-80807 München Tel. 089-189174474 · Fax 089-54058884
Date/日期	2021 年 07 月 09 日	Date/日期	2021 年 07 月 09 日

Annex 1: Business License, Permits and Certificates of Party A

附件一：甲方营业执照、许可证、资质证书

Annex 2: List of Medical Devices

附件二：医疗器械产品清单

Name of Medical Device 医疗器械名称	Category 分类
Medical Compression Hosiery for Varices	**I**

Party A 甲方	**Zhejiang Rongrong Hosiery Co., Ltd.** 浙江荣荣袜业有限公司	**Party B** 乙方	**MedPath GmbH** 医通有限责任公司
Signature/签字		Signature/签字	
Stamp/盖章		Stamp/盖章	MedPath GmbH Mies-van-der-Rohe-Strasse 8-D-80807 München Tel.089-189174474 -Fax 089-54858884
Date/日期	2021 年 07 月 09 日	Date/日期	2021 年 07 月 09 日

Annex 3: Information of Primary Contact

附件三：联络人信息

Party A/甲方

Name of Primary Contact:
联络人姓名： 马旭荣

Title:
职务：

Tel/电话: +86-579-85231018 +86-15924266280

Fax/传真: +86-579-85231018

Email/电子邮箱: 563231439@qq.com / 793634201@pp.com

Address:
地址： 浙江省义乌市北苑街道夏荷路 80 号

Party B/乙方

Name of Primary Contact:
联络人姓名： Mei, Zheng

Title: Person Responsible for Regulatory Affair
职务： 法规负责人

Tel/电话: +49(0)89 189174474

Fax/传真: +49(0)89 5485 8884

Email/电子邮箱: info@medpath.pro

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地址：