# EU Representative Agreement

According to <Regulation (EU) 2017/745> MDR

Document Number: JH-ERA-MDR-21241V00

This agreement will be valid for 5 years from 2021-5-20 to 2026-5-19. Part A could choose to renew the agreement by then, otherwise this agreement will be terminated automatically.
此合同有效期为5年，自2021年5月20日至2026年5月19日。到期后由甲方选择续约或合同自动失效。

| Part A (甲方) | |
|---|---|
| Name(名称): | Wenzhou Joysee Eyewear Company Ltd. |
| Add(地址): | 301,B3/BLDG.,NO.81 ZHONGHUI/RD.,LOUQIAO INDUSTRIAL PARK, OUHAI,WENZHOU 325000 CHINA |
| Zip Code(邮编): | 325000 |
| Contact Person(联系人): | XiaLin Lin |
| Tel/Fax(联系电话/传真): | 0086-13456050627 |
| E-mail(邮箱): | joyseeeyewear@hotmail.com |
| Party B (乙方) | |
| Name(名称): | Luxus Lebenswelt GmbH |
| Add(地址): | Kochstr. 1, 47877, Willich, Germany |
| DIMDI Code: | DE/0000047791 |
| Tax Number: | DE305829099 |
| Contact Person: | Lin Sun |
| Tel/Fax: | 0049-1715605732 |
| E-mail: | Info.m@luxuslw.de |
| Competent authority(主管当局信息) | |
| Name | Bezirksregierung Düsseldorf, Dezernat 24 |
| Federal state | Nordrhein-Westfalen |
| City | Düsseldorf |
| Postal code | 40474 |
| Street, house no. | Cecilienallee 2 |
| Phone/Fax | +49-211-4750 / +49-211-4752671 |
| E-mail | dez24.mpg@brd.nrw.de |

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Only used for

Party A hereby appoints Party B to be its European Authorized Representative as defined in Article 2 (32) MDR in the EU for all medical devices as listed in table below, the Products are medical devices within the definition in accordance to Article 2 (1) and Article 2 (2) MDR and shall be classified according to Annex VIII of the MDR. Party B accepts the appointment as European Authorized Representative.
Note: This agreement supersedes any prior agreements between the parties regarding to European Authorized Representation.
甲方按照MDR第2(32)条款任命乙方为其下表所列医疗器械的欧盟授权代表，乙方接受甲方任命,为甲方欧盟授权代表。
注：本合同取代双方所有之前有关欧盟授权代表的协议。

| No. | Product Name/产品名称 | Models/型号 | Classification/ 分类 |
|---|---|---|---|
| 1 | OPTICAL FRAMES | | I |
| 2 | Reading glasses | | I |

## I. Obligations and Liabilities of Party A 甲方职责和义务

1. Party A (as the legal Manufacturer) shall be responsible for meeting the requirements of Article 10 of MDR "General obligations of manufacturers".
甲方（作为法定制造商）有责任确保满足 MDR 第 10 条"制造商的义务"的要求。

2. Party A (as the legal Manufacturer) shall be responsible for the conformity assessment procedure of the Products in accordance with Article 52 MDR and all other applicable European laws, rules and regulations, relevant to the Products. Party A (as the legal Manufacturer) shall keep records for full traceability of all sales of Products made into the EU-market for at least 10 years (for implantable devices at least 15 years) after the last device covered by the relevant EU declaration of conformity has been placed on the market. Party A shall provide these records to Party B no later than 2 working days after a request to receive such records from any EU Competent Authority.
甲方（作为法定制造商）应负责确保产品的合格评定程序符合 MDR 第 52 条以及与产品相关的所有其他适用的欧洲法律，法规和规章的要求。甲方（作为法定制造商）应保留所有产品在欧盟市场上销售的完整追溯记录，直到最后一个被相关欧盟符合性声明涵盖的产品投入市场后至少 10 年（对于植入式器械则至少 15 年）。如欧盟主管机关要求，甲方应在 2 个工作日内向乙方提供这些记录。

3. Party A assures to provide technical files of each product category with CE mark to Party B no later than 30 days after approval of CE certification or sign EU Declaration of conformity for Class I products. The technical files should be the electronic copy (PDF/WORD/JPG/ vision), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files as following:
甲方确保在取得证书或者1类产品签署EU符合性声明之后的30天内向乙方提供每一类加贴CE标志的产品的技术文档。甲方必需提交电子文件，文件可以是PDF/WORD/JPG/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如下：
(a) EU Declaration of conformity, EU符合性声明
(b) Notified Body certification (where relevant), 公告机构证书（适用时）

(c) Technical documentation according to Annex II and III of MDR, MDR附录II和III要求的技术文档
(d) Post market surveillance process, vigilance system and complaints control procedure. 上市后监督过程和数据、警戒系统、投诉处理控制程序

4. Party A assures to provide label, packaging and instructions for use of each product category with CE mark to EU users in all languages requested by the countries where the device is marketed.
甲方应确保提供给欧洲使用者的加贴CE标志的产品标签、包装和说明书符合所上市国家要求的语言。

5. Before each product listed in this agreement is placed into the EU market, Party A must notify Party B and provide Party B with product labeling updated, details of any importer and distributors in EU.
本协议所涉及的每个产品在投放到欧盟市场之前，甲方必须通报给乙方，并且应向乙方提供最新的产品标签文件和欧盟进口商，经销商的信息。

4. If any accident of products happens within boundary of E.U., 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 Regulation (EU) 2017/745 MDR (If MDR requirements cannot be implemented due to force majeure, it should refer to requirements of MDD 93/42/EEC (MDD)) 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 send notification to the email of Party B as stipulated in Article 2 hereof in two calendar days 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 in writing within one week after relevant accident happened.
如果产品在欧盟境内发生事故，甲方应及时配合乙方调查原因，并同乙方一起负责完成初始报告。甲方应按照 MDR 要求（如果 MDR 的要求因不可抗力而导致的无法实施，则应参考 MDD 的要求）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，甲方须立即在两个自然日内以电子邮件形式发送至上述第2条中的电子邮箱中；并需要对事故、准事故的调查、分析和处理结果的报告，用电子邮件或书面方式在相关事件产生后一周内通知乙方。

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 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。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，乙方可以要求甲方提前支付相应的款项，在该款项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。

6. Party A promises that Party A will bear all responsibility for any accidents, claims or other disputes

caused by Party A's products. 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.

If due to legal reasons, Party B must bear compensation, product recalls, disputes and other events for Party A's products, Party A shall bear Party B's human resources expenses and cash and currency expenses.

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.

This clause is valid forever after signing this agreement and will not be invalidated by the termination of this agreement.

甲方承诺，甲方应承担其产品带来的任何事故、索赔或其他纠纷的责任。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。

如因法规原因，乙方必须为甲方产品承担赔偿、产品召回、纠纷处理等事件，甲方应承担乙方的人力资源开支和现金货币开支。

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。

此项条款自合同签署后永久有效，不因合同有效期终止而失效。

7. Party A should appoint one persons as the primacy linkman who connect with Party B and deal with the normal daily grind according to this agreement. Information of both Parties' linkman should be written in Page one. The information delivered to the primacy linkman who connect with Party A by Party B shall be deemed as delivery to Party A and the instruction provided by the primacy linkman who connect with Party A shall be deemed as the instruction from Party A.

Party A shall establish and have available a Person Responsible for Regulatory Compliance according to Article 15 MDR.

甲方需指定一人，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第一页。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。

甲方应根据 MDR 第 15 条设立并配备专门的合规责任人。

8. Party A should establish a Product Liability insurance with a coverage appropriate to the risk associated with the Products and the volume of sales in the EU, which shall cover Product Liability cases related to the Products and shall remain in force while this contract remains in force and effect or for at least 10 (ten) years after the delivery of the last Product, whichever date may be later. Such insurance shall cover Part B in its role as AR against all potential Product Liability claims by a third party.

Upon request by Party B, the Party A shall submit a copy of the insurance policy in the English language.

甲方应购买产品责任保险，并确保该保险的涵盖范围跟产品风险和产品在欧盟的销售量相匹配。该保险应涵盖与产品有关的产品责任案件，并在本合约有效期间或最后一个产品交付后至少 10（十）年持续有效，以较晚的日期为准。 此保险应以乙方作为欧代的形式承担乙方可能要依法对第三方承担的所有产品责任赔偿。

若乙方要求，甲方应提供该保险单英文版本的副本。

9. Party A shall fully realize the risk of placing its products into EU market without notification /registration. If it caused by Party A, such as delay, admittance or conceal of files submission, Party A should take the aftereffects such as warning, penalty or even the results that the CE certificate will be withdrawn, and the distribution of its products in EU market will be prohibited.
甲方需要充分认识到本企业产品没有通报/注册就销售欧盟市场所带来的风险。如果由于甲方延误、疏漏或者隐瞒而造成的原因，发生产品没有登记备案就进入欧盟市场的，甲方将自行承担其后果，如警告、罚款，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。

## II. Obligations and Liabilities of Party B 乙方的职责和义务

1. Party B should comply with and perform the notification/registration obligations laid down in Article 31 of MDR, if EUDAMED is not available, Party B will comply with the notification/registration guidance of its local Competent Authority.
按照 MDR 第 31 条， 乙方应遵守和执行通报/注册的职责，在 EUDAMED 数据库可以使用前，乙方应符合当地主管机关的通报/注册要求。

2. Party B shall reserve technical files of each category of party A's products with CE mark. The technical files shall be reserved for at least ten years after manufacturing of the last batch of products. Once competent authority needs the technical files (including new edition of the 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 workdays.
乙方应保留甲方每一大类获得 CE 标志产品的技术文档，该文档至少保存至最后一批产品出厂后十年。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. Party B shall verify that the EU declaration of conformity and technical documentation. If the verification result shows that technical documents do not meet the requirements of Annex II and III of MDR, Party B may request Party A to make corrections and supplements.
Party B have the obligation to send them to competent authority if competent authority request. 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"，乙方应该对 EU 符合性声明和技术文档进行确认，如果确认结果显示技术文档不符合 MDR 附录 II 和 III 的要求，乙方可以要求甲方进行更改或补正。
乙方有义务在主管机关要求时向其提供技术文档，乙方应对技术文档进行维持和保密。

4. If any serious accident of products happen within boundary of E.C., Party B shall notify Party A within two calendar days of complaint or feedback on Party A's products and assist Party A to execute vigilance system of medical device products, and also make the initial report together with Party A. Party B shall then present the initial report, investigation results and the final report to competent authority of country in which the accidents happen.
如果带有 CE 标志的产品在欧盟境内发生严重事故，乙方应在收到有关甲方产品的投诉或反馈信息两个自然日内通知甲方，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事故发生国主管当局提供。

5. Party B shall establish and have permanently and continuously at its disposal a Person Responsible for Regulatory Compliance who has the respective qualification.
Party B shall appoint one persons as the primacy linkman whose responsibility is to connect with Party A and deal with the normal daily grind according to this agreement. The information of both Parties' linkman was written in first page of this contract.
乙方应建立并拥有永久且持续可用的，且具有相应资格的合规责任人。
乙方需指定一人，作为甲、乙双方的第一联络人，主要职责是与甲方共同协调、处理本协议条款规定范围内的日常工作。双方联络人的联络方式记录在本协议的第一页。

## III. 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 provided by Party B.
就乙方提供本协议规定的相关服务，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 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约定相关费用。

## IV. Change of authorised representative 欧盟授权代表的变更

1. This agreement will be terminated automatically after the data of termination of this agreement.
本合同约定终止日期后，本合同自动终止。

2. If Party A wish to change Luxus lebenswelt GmbH with another authorised representative during this period, Party A should provide Luxus lebenswelt GmbH with the details of the new authorised representative and the date it takes over responsibility.
如果甲方在此期间希望更换 Luxus lebenswelt GmbH 为另一个欧盟授权代表，甲方应向 Luxus lebenswelt GmbH 提供新的欧盟授权代表的信息和职责接管的日期。

## V. Others 其他

1. 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。

2. Contract Language 合同语言
This agreement exists in English and Chinese language. The Chinese version is an exact duplicate of the English version, and have the same legal effect.
本协议为中文和英文的对照版本，中文版本和英文版本内容完全一样,具有同样的法律效力。

3. 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。

4. This agreement is subject to the requirement specified in the <Regulation (EU) 2017/745> MDR. Should there be any conflicts between this agreement and <Regulation (EU) 2017/745> MDR shall be followed as standards. If the regulation above update or change, Party A and Party B should actively negotiate and communicate to ensure that the requirements of the new regulation are met.
本协议受《欧共体关于医疗器械的 2017/745 法规》约束。如本协议条款与上述法规为准。如上述法规发生更新或变更，甲乙双方应积极协商和沟通，确保持续满足新法规的要求。

5. During the implementation of the agreement, this agreement will be terminated automatically when:
在协议执行期间内，下列日期为本协议的自动终止日期：
(a) The day upon Part A's CE Certificate be withdrawn temporarily, be closed or be recalled by the notified body. When the above mentioned things happen, Party A is obligated to accomplish the following processes to avoid the further consequences:
甲方的 CE 证书因事故被发证机构暂时吊销/关闭/收回的。以上事实一旦发生，甲方需主动配合乙方做好以下善后工作，否则将承担由于不作为或者作为不当而产生的所有责任：

- 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。
- Written statement of non-sales if there are no products under the withdrawn, closed or recalled CE Certificate exporting to EU 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。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。）

(b) Party A can not provide the required technical file to Party B within 30 days after approval of the CE certification or sign EU declaration of conformity for Class I products. During 60 days from the date of this agreement terminated, Party A could transact the routine affairs as the authorized European Representative while Party A could appoint new European Representative and change the CE certification. Party B should report the invalid agreement to the notify body for record.
甲方在认证结束取得证书之后或者1类产品在签署符合性声明后的30天内，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。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。

(c) Party A doesn't payoff the service fee according to this agreement and refuse to explain on the deadline.
甲方没有按协议规定的最后期限内付清欧盟代表服务费用，又不作解释的。

No other rights or obligations are applied to Party A or Party B other than specified in this agreement.
除本协议外，甲、乙双方不赋予其他权利和义务。

PART A: **Wenzhou Joysee Eyewear Company Ltd.**

Signature(签字): Allen Zhu
Company Stamp(公章):
Date(日期):

PART B: **Luxus Lebenswelt GmbH**

*For and on behalf of*

Signature(签字):
Company Stamp(公章): LUXUS LEBENSWELT GMBH
MEDICAL AMAZON Kochstr. 1, 47877 Willich, Germany
Date(日期):

Only used for EU Representative Agreements