MOBICLINIC

MASCARILLAS QUIRÚRGICAS

IIR

CE

FABRICADAS SIGUIENDO **NORMA EN 14683:2019**.
TEST REPORT HOMOLOGADO POR SGS.

Características Mascarillas Quirúrgicas IIR:

175mm x 95mm

≥98%
Eficacia de Filtración Bacteriana/ BFE

→ **≥99,8% SEGÚN ENSAYOS SGS**

BAJA RESISTENCIA RESPIRATORIA
(presión diferencial < a 60 Pa/cm²)

≥16
Presión de resistencia a las salpicaduras/ kPa

3 Capas

UN SOLO USO

No esterilizadas

Estas mascarillas presentan **marcado CE** y están fabricadas conforme a Directiva 93/42/CEE relativa a productos sanitarios y siguiendo **norma EN 14683:2019**. Test Report homologado por SGS.

Packaging:

BOLSA 25 UDS

29*17 cm

REF. QF - 00119/41

→ **CAJA MÁSTER**
2.100 UDS
(84 BOLSAS)
53*43*46 cm

REF. QF - 00119/41-2100

CAJA 50 UDS

21*10*9 cm

REF. QF - 00119/50

→ **CAJA MÁSTER**
2.500 UDS
(50 CAJAS)
53*43*46 cm

REF. QF - 00119/50-2500

EC Declaration of Conformity

Manufacturer:

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable medical face mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Foshan, March 30th, 2020
Place, date

Liao Yufeng
佛山和沣医疗器械有限公司
FOSHAN HEFENG MEDICAL EQUIPMENT CO., LTD.
General manager
Legally binding signature, Function

TIMBRE DEL ESTADO

0,03 EUROS

TRES CÉNTIMOS DE EURO

CN8174946

中国认可
国际互认
检测
TESTING
CNAS L0599

CLASE 8.ª

Informe de la prueba **Fecha: 18 de junio de 2020** **Página 1 de 3**

La(s) siguiente(s) muestra(s) ha(n) sido presentada(s) e identificada(s) en nombre del cliente como:

Descripción de la muestra	:	
Nº de referencia interno de SGS	:	
Nº de modelo	:	
Color de la muestra	:	(A)AZUL claro
Fabricante	:	
País de origen	:	China
Nº Artículo	:	
Nº de lote	:	No se ha facilitado
Prueba realizada	:	Prueba(s) seleccionada(s) a petición del solicitante
Fecha de recepción de la muestra	:	19 de mayo de 2020
Período de la prueba	:	19 de mayo de 2020 - 18 de junio de 2020
Resultado(s) de la prueba	:	A menos que se indique lo contrario, los resultados que se muestran en este informe de la prueba se refieren únicamente a la(s) muestra(s) analizada(s), para más detalles, véase(n) la(s) siguiente(s) página(s).

Firmado por y en nombre de
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

[firma ilegible]
Sara Guo (Ejecutiva de Cuentas)

[firma ilegible]
Dongjing Liu (Firmante Autorizado)

MARC CALBET PRADES
Traductor e Intérprete Jurado de Inglés
Nº 6521

[sello: Servicios de Prueba e Inspección (resto del sello en idioma chino)]

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233 t (80-21) 61402666 f (80-21) 64958763 www.sgsgroup.com.cn
e sgs.china@sgs.com

Resultado de la prueba CLASE 8.ª

EN 14683:2019+AC:2019 Mascarillas quirúrgicas: requisitos y métodos de prueba

Cláusula 5.2 Requisitos de cumplimiento

Cláusula 5.2.2 Eficiencia de la filtración bacteriana (BFE por sus siglas en inglés)*

(EN 14683:2019 Anexo B)

	1#	2#	3#	4#	5#
(BPE), %	99,9	99,9	99,9	99,9	99,9

Observaciones: Requisitos de cumplimiento: Tipo I≥95%, Tipo II≥98%, Tipo IIR ≥98%

* Esta norma de ensayo no está dentro del ámbito acreditado en el centro de ensayos de SGS Shanghái, siendo llevada a cabo por un laboratorio externo acreditado por la CMA (China Metrology Accreditation - Acreditación de Metrología de China).

Cláusula 5.2.3 Respirabilidad

(EN 14683 :2019+AC:2019 Anexo C)

MARC CAUBET PRADES
Traductor e Intérprete Jurado de Inglés
Nº 6521

Muestra: A

Número y ubicación de la prueba	:	5 zonas aleatorias para cada muestra (mascarilla)
Parámetros de acondicionamiento	:	Mínimo de 4 horas a 21±5oC y 85±5% R.H.
Zona de la prueba	:	4,9 cm2
Tasa de flujo	:	8 l/min

	1#	2#	3#	4#	5#
Presión diferencial ΔP (Pa/cm2)	30	30	27	30	30

Observaciones: Requisitos de cumplimiento: Tipo I<40 Pa/cm^2, Tipo II<40 Pa/cm^2, Tipo IIR<60 Pa/cm^2

Cláusula 5.2.4 Resistencia a las salpicaduras

(ISO 22609 :2004, Presión 16,0 kPa)

Penetración en la superficie interior							
1#	2#	3#	4#	5#	6#	7#	8#
Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado
9#	19#	11#	12#	13#	14#	15#	16#
Aprobado	Aprobado	Aprobado	Fallido	Aprobado	Aprobado	Aprobado	Aprobado
17#	18#	19#	20#	21#	22#	23#	24#
Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Fallido	Aprobado
25#	26#	27#	28#	29#	30#	31#	32#
Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Aprobado	Fallido
Número de aprobados:			29				
Resultado general:			Aceptable				

Observaciones:

1) Requisitos de cumplimiento Tipo I: N/A, Tipo II: N/A, Tipo IIR: ≥16,0kPa
2) La distancia de la superficie de la superficie de la mascarilla quirúrgica hasta la punta de la cánula es 300±10mm.
3) Condiciones y temperatura de la prueba (21±5)°C, humedad relativa (85±10)%
4) Se cumple un límite de calidad aceptable del 4,0% para un plan de muestreo único cuando 29 o más de los 32 ejemplares sometidos a prueba muestran resultados de aprobación

[sello: Servicios de Prueba e Inspección (resto del sello en idioma chino)]

CLASE 8ª

Cláusula 5.2.5 Limpieza microbiana
(EN 14683:2019+AC:2019 Anexo D y EN ISO 11737-1:2018)

	1#	2#	3#	4#	5#
CFU/g	1	1	2	4	5

Observaciones: Requisitos de cumplimiento: Tipo I≤30 CFU/g, Tipo II≤30 CFU/g, Tipo IIR≤30 CFU/g

Foto de muestra

La declaración de conformidad que consta en este informe de la prueba se basa únicamente en los valores medidos por el laboratorio y no tiene en cuenta sus respectivas incertidumbres.

Fin del informe

[sello: Servicios de Prueba e Inspección (resto del sello en idioma chino)]

MARC CAUBET PRADES
Traductor e Intérprete Jurado de Inglés
Nº 6521

TIMBRE DEL ESTADO

ON8374949

CLASE 8.ª

Don Marc Caubet Prades, Intérprete Jurado de inglés, en virtud de título otorgado por el Ministerio de Asuntos Exteriores, Unión Europea y Cooperación de España, certifica que la que antecede es una traducción fiel y completa al español de un documento redactado en lengua inglesa.

En Madrid, a 22 de septiembre de 2020

Marc Caubet Prades, Sworn Translator of English, appointed by the Spanish Ministry of Foreign Affairs, European Union and Cooperation, does hereby certify that the preceding translation is a complete and faithful rendering in Spanish of the original in English.

Madrid, 22 September 2020

MARC CAUBET PRADES
Traductor Jurado de Inglés / English Sworn Translator
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MARC CAUBET PRADES
Traductor e Intérprete Jurado de Inglés
Nº 6521

Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

EU Representative Agreement

Document Number: JH-ERA-20473VOO

This agreement will be valid for from 2020.3.30 to 2024.5.26 . Part A could choose to renew the agreement by then, otherwise this agreement will be terminated automatically.此合同有效期自2020年3月30日至2024年5月26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):	Foshan Hefeng Medical Equipment Co., Ltd.
Add(地址):	No.4-1，Leqiang Road, Leping Town, Sanshui District, Foshan City, Guangdong Province, China
Zip Code(邮编):	528100
Contact Person(联系人):	NANCY HE
Tel/Fax(联系电话/传真):	+8675787781123
E-mail(邮箱):	KY07@NHKAIYANG.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

Party A hereby appoints Party B as the authorized European Representative for their Medical Device with CE mark, 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, the appointed product categories set out in below form:
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,双方签署下列协议,委托的产品类别见下表：

No.	Product Name/产品名称	Models/型号	Classification/分类
1	Disposable medical face mask	HF-SU01，HF-SU02,	I

		HF-SU03, HF-SU04, HF-SM01 , HF-SM02 , HF-SM03 , HF-SM04	
2	Medical protective mask	HF-MP01 , HF-MP02 , HF-MP03 , HF-MP04	I

I. Obligations and Liabilities of Party A

甲方职责和义务

1. Party A assures to provide the updated technical files of each product category with CE mark to Party B. If Party A can not 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/ 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。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：
   (i) Declaration of conformity, 符合性声明
   (ii) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed), 标签、包装、说明书副本（所有上市国家要求的语言的版本）
   (iii) Notified Body certification (where relevant), 公告机构证书（适用时）
   (iv) Post market surveillance process and data, vigilance reports and complaints, processes and data, 上市后监督过程和数据、警戒报告以及投诉、处理和数据
   (v) Technical documentation relevant to market surveillance investigation being undertaken by the Member State, 与欧盟成员国上市监督调查有关的技术文件
   (vi) Relevant clinical data / notification, 相关的临床数据/通知
   (vii) Details of any distributors / suppliers putting the CE marked devices on the market, 经销甲方CE标志医疗器械的经销商/供方细节
   (viii) Incident reports and corrective actions taken. 事故报告及采取的纠正措施
2. 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 and details of any distributors /suppliers in EU, otherwise this agreement will be terminated automatically, Party A should take on any aftereffect by itself.
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经销商/供方的信息，否则本协议自动失效，甲方承担由此而引起的所有后果。

3. 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: info.m@luxuslw.de.
产品如有改变，技术文件如有更新，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.m@luxuslw.de。

4. 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 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及 EEA 和瑞士、土耳其之发生事故或者准事故（包括在上市前的临床调查阶段发生的严重不良事故（详见"Guideline for Authorized Representatives（MEDDEV 2.5/10）(2012 年 1 月)"），甲方应及时配合乙方调查原因，并同乙方一起负责完成初始报告。甲方应在《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 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。

6. Party A should keep the complete sales list of all of the products exporting to any area of E.U. EEA and Switzerland (including the OEM products) by electrical documents in English at least 5 years, 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和瑞士之官方的调用、检查。甲方要对提供的数据其准确性、真实性负责。

7. 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。

8. 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.
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。

9. Party A shall fully realize the risk of selling its products to EU, EEA and Swiss, Turkey market without product registration to relevant competent authority of E.C. 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, EEA, and Swiss, 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 和瑞士之市场的，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及 EEA 和瑞士、土耳其之的后果。

10. Party A shall notify of the intention to Party B to carry out a clinical investigation for MDD or AIMDD, and the intention to carry out a performance evaluation for IVDD performed in EU, EEA and Swiss,Turkey.
甲方应通知乙方在欧盟、EEA 和瑞士及土耳其对医疗器械或者有源植入性医疗器械进行临床试验的计划，以及对体外诊断试剂进行性能评估的计划。

11. Party B is released by Party A of any liability relating to the medical devices 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

12. 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。

13. 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。

II. Obligations and Liabilities of Party B

乙方的职责和义务

1. About the register for Party A's products with CE mark to relevant competent authority of E.C., Party A shall apply it in written to Party B and supply all the files and forms needed. Party B shall review it within 7 working days, and submit to competent authority of the country in which Party B is located (Germany) within 5 days. If Party A's application is returned/rejected by Party B or the competent authority for the contents of the submitted files, the above schedule will be adjusted accordingly.
   If it needs any expenditure by the competent authority, only after getting Party A's approval, then Party A can take on the payment. If Party A's products register fails by Party B's reason, according to Germany/EU relevant laws Party B will be given a warning, penalty and even the qualification of the European Representative will be revoked.
   如果甲方已加贴 CE 标志的产品按欧盟相关规定必须需要办理 CE 产品欧盟登记备案的，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 7 个工作日完成初审，5 个工作日内提交乙方所在国德国主管当局审核申请登记备案的文件。但是由于甲方提交文件内容方面的原因被乙方或者当局退回/拒绝的申请，不在此时间规定之列。
   德国主管机构审核上述登记备案如需要收取相关费用的，需经甲方同意方可由乙方代为支付。如果由于是乙方的原因，甲方的申请登记备案手续失败而影响企业产品正常进入欧盟市场的，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. 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 a 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 have 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 notify any information about the products with CE mark within the Boundary of E.C., including any claims of customers and the competition company that produce the same CE marked products, to Party A.
   乙方应将有关 CE 产品在欧盟境内的任何消息(包括客户投诉和同类竞争企业)及时通知甲方。
5. 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。

6. 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。
7. Party B shall assist Party A to comprehending the condition of the same products within boundary of E.U, and send the related information to Party A in time.
乙方协助甲方了解欧盟市场同类产品的情况，并及时反馈给甲方。
8. Party B shall keep all technical files and information of Party A's in confidentiality.
乙方应对甲方技术文档和资料保密。

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. **Others**

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.
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。
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。

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. 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 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。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。

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, EEA and Swiss, 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。）

(b) Party A can not 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.
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。

(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: Foshan Hefeng Medical Equipment Co., Ltd.

Signature(签字): Liao Youfeng

Company Stamp(公章):

Date(日期): November 26th, 2020

PART B: Luxus Lebenswelt GmbH

For and on behalf of
LUXUS LEBENSWELT GMBH
Kochstr.1, 47877 Willich, Germany

Signature(签字):

Company Stamp(公章):

Date(日期):

Authorized Signature:
Simon Qian
Only used for EU Representative agreements