CE CE

Declaration of Conformity

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer

Name: Hefei Hanchin Medical Supplies Co.,Ltd

Address: No.5 Weiwu Road, Shuangfeng economic and technological development zone, Hefei, China.

European Authorised Representative

Name: LiKing GmbH

Address: Fraunhofer StraBe 7, 04178 Leipzig

Product

Name: Sterilization Pouch

Model/Specification: 65mm*35mm*200mm, 50mm*200m, or Customized

SRN: -

Basic-UDI-DI: -

Classification: I

Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III

We confirm our product meets the requirements of EU Medical Device Regulation (2017/745) and the following harmonized standards.

EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Signature Position: Wang Wei/GM

Date: 2020.9.17

Place: Anhui

协议编号 ERP2020AG480

Authorized Representative Agreement (MDR)

授权代表协议（医疗器械法规）

Party A: Hefei Hanchin Medical Supplies Co.,Ltd

Add: No.5 Weiwu Road,Shuangfeng economic and technological development zone Hefei China

Contract: wang wei

Tel: 0551-62733620

Fax:

E-mail: sales@hanchinmedical.com

Party B: LiKing GmbH

-

Add: Fraunhofer StraBe 7, 04178 Leipzig

-

Contract: NX-Kimi Yang

Tel: 0049 341 580 963 70

Fax:

E-mail: Spica.nx@gmail.com

Advertiser Code: DE/0000049097

Party A has defined the scope of business and the fees.
For details, see Annex 1 "Description of Operations".

甲方已明确业务范围以及收费标准。
详情，见附件 1《业务说明》。

Party B has set out the scope of the operations and the fees.
For details, see Annex 1 "Description of Operations".

乙方已阐明业务范围以及收费标准。
详情，见附件 1《业务说明》。

Party A undertakes that the information of device is true and correct.
For details, see Annex 2 "Information of Device".

甲方保证器械信息真实无误。
详情，见附件 2《器械信息》。

Party B has confirmed the information of device.
For details, see Annex 2 "Information of Device".

乙方已确认器械信息。
详情，见附件 2《器械信息》。

Party A hereby appoints Party B as a single Authorized Representative for the above devices.

甲方在此任命乙方作为上述器械的唯一授权代表。

Party B hereby declare that Party B meets all the requirements set for European Authorized Representation in the *Regulation (EU) 2017/745 on medical device*, The *Guideline for Authorised Representatives in Article 2(32)MDR in the EU for all medical devices as*

listed in Appendix A, the Guidelines on a Medical Devices Vigilance System according to Articles 83-86 MDR, etc.

乙方在此声明符合现有规定对授权代表的要求，如《医疗器械法规》、《授权代表指南》、《医疗器械警戒系统》等。

Both Parties sign this Agreement.

Party B is released by Party A of any liability relating to the medical devices manufactured by Party A. Party A will be fully responsible for the performance of its products and will hold Party A against any liability claim arising from the use of the products manufactured by Party A.

In addition to this Agreement, both Parties will comply with the additional requirements of the regulations of the listed Member States.

双方签署本协议。

甲方承诺，乙方不为用户对甲方生产的医疗器械的索赔承担任何责任。

甲方为其产品性能承担全部责任，并将确保乙方不会因为甲方生产的产品在使用过程中产生的任何责任索赔而承受损失。

除本协议外，双方还将遵守上市成员国的法规的额外要求。

Party A / 甲方

1. Party A is obliged to submit the information of device by a deadline. Where necessary, Party A is obliged to assist Party B in registering device information with the Competent Authorities.
   For details, see Annex 1 "Description of the Operations".
   甲方有义务在 30 天内提交器械的相关资料。在需要时，甲方有义务协助乙方在主管部门处登记器械信息。
   详情，见附件 1《业务说明》。

2. Party A is obliged to notify of the intention to carry out a clinical investigation to Party

Party B / 乙方

1. Where necessary, Party B is obliged to register with the Competent Authorities of the Member State and to inform the Competent Authorities of the address of the registered place of business of Party A and the description of the devices concerned.
   在需要时，乙方有义务向成员国主管部门登记，并向主管部门告知甲方注册营业地的地址和有关器械的说明。

2. Party B is obliged to notify of the intention to carry out a clinical investigation to the

B. Party A is also obliged to notify when it starts and ends and to make available the written report of the clinical investigation.

甲方有义务向乙方告知进行临床试验的意图，并向乙方告知临床试验的起始时间、提供临床试验的书面报告。

Competent Authorities of the Member State in which the investigations are to be conducted. Party B is obliged to notify when it starts and ends and to make available the written report of the clinical investigation.

乙方有义务向主管部门通知器械临床试验的意图，并向计划调查的主管部门告知试验的起始时间、提供试验的书面报告。

3. Party A is obliged to provide Party B with the correct and necessary information.
For details of the relevant information, see Annex 3 "Information List".

甲方有义务向乙方提交正确的必要信息。
对提交信息的详情，见附件 3《信息清单》。

3. In the event that Party A is unable to provide the necessary information, Party B is obliged to terminate the agreement between parties.

在甲方无法提供必要信息时，乙方有义务解除双方的协议。

4. When the information covered in Annex 3 changes, Party A is obliged to immediately submit or update the relevant information to Party B.

当附件 3 中涉及的信息发生变动时，甲方有义务及时向乙方提交或更新相应的信息。

4. When necessary, Party B has the obligation and right to distribute Party A's information mentioned in Annex 3 directly to the Competent Authorities.

在需要时，乙方有义务且有权直接向主管部门分发附件 3 中涉及的甲方信息。

5. Party A is obliged to keep certain information at the disposal of the Competent Authorities, such as sale lists, technical documentation, declarations of conformity.
For details, see Annex 3 "Information List".

甲方有义务在规定的期限内保存部分重要信息，如销售清单、技术文件、符合性声明等，以供主管当局调用。
详情，见附件 3《信息清单》。

6. Party B is obliged to keep certain information at the disposal of the Competent Authorities, such as sale lists, technical documentation, declarations of conformity.
For details, see Annex 3 "Information List".

乙方有义务在规定的期限内保存部分重要信息，如销售清单、技术文件、符合性声明等，以供主管当局调用。
详情，见附件 3《信息清单》。

7. Party A is obliged to provide Party B with additional information and documentation

6. Party B is obliged to provide information and documentation that a market

that a market surveillance authority may require for the purpose of market surveillance.

For details, see Annex 3 "Information List".

甲方有义务向乙方提供市场监督机构为市场监督目的而可能要求的额外信息和文件。

详情，见附件 3《信息清单》。

surveillance authority may require for the purpose of market surveillance.

乙方有义务提供市场监督机构为市场监督目的而可能要求的信息和文件。

7. Party A is obliged to produce device labels as required and to end any infringement of the CE marking that occurs.

甲方有义务按要求制作器械标签，且有义务终止发生的有关 CE 标志的侵权事件。

7. Party B is obliged to inform Party B of any infringement of the CE marking and the action required to end it.

Party B authorizes Party A to use the information of Party B on the device label.

乙方有义务向甲方通知有关 CE 标志侵权行为的信息，并告知甲方终止侵权行为所需的措施。

乙方授权甲方在器械标签上使用乙方信息。

8. Party A is obliged to pay Party B for the expenses incurred by additional business activities outside the scope of the Agreement.

甲方有义务向乙方支付协议范围外的额外业务活动所产生的费用。

8. When Party B assists Party A with additional business activities outside the scope of the agreement, Party B shall be entitled to charge an appropriate fee.

当乙方协助甲方处理协议范围外的额外业务活动时，有权收取适当的费用。

9. Party A is obliged to appoint an emergency contact to Party B. When the contact information changes, Party A is obliged to inform Party B immediately.

For details, see Annex 4 "Emergency contact"

甲方有义务向乙方指定一名紧急联系人。当联系人信息发生更改时，甲方有义务立即告知乙方。

详情，见附件 4《紧急联系人》。

9. Party B is obliged to appoint an emergency contact to Party A. When the contact information changes, Party B is obliged to inform Party A immediately.

For details, see Annex 4 "Emergency contact"

乙方有义务向甲方指定一名紧急联系人。当联系人信息发生更改时，乙方有义务立即告知甲方。

联系人信息详情，见附件 4《紧急联系人》。

Party A & B / 甲方和乙方

1. Party A is obliged to inform Party B of all matters that may be connected to the devices placed on the market in the EU (including information outside the EU).
   Party B is obliged to inform Party A of all matters that may be connected to the devices placed on the market in the EU (e.g. market decisions taken by the Competent Authorities for the devices, accidents, events, etc.).
   Both Parties are obliged to communicate to each other at all times all information that they know that may be connected to the devices placed on the market in the EU

   甲方有义务向乙方通报可能与投放至欧盟市场上的器械有关的所有事项（含欧盟境外的信息）。
   乙方有义务向甲方通报可能与投放至欧盟市场上的器械有关的所有事项（如，主管部门对器械做出的市场决定、事故、事宜等）。
   双方有义务随时互相传达各自得知的所有可能与投放至欧盟市场上器械有关的信息。

2. Where a Member State ascertains that a medical device, when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.
   Party B is obliged to immediately communicate such measures to Party A and advise Party A as to the implications of this decision, when Party B is informed by the Competent Authorities.
   Party B is obliged to inform Party A of the follow-up of such measures (e.g. the decision of the European Commission), when Party B is informed by the Competent Authorities.

   如果上市成员国确定，一种器械在正确安装、维护和符合预期用途的情况下，仍可能会危害患者、使用者、其他人员的健康或财产的安全，则应采取一切适当的临时措施，将这种器械撤出市场，并禁止或限制该器械投入市场。
   当主管部门告知乙方时，乙方有义务立即向甲方传达上述的措施，并向甲方告知有关决议可能带来的影响。
   当主管部门告知乙方时，乙方有义务向甲方传达上述措施的后续情况（如欧盟委员会的裁定）。

3. In the event of a medical device accident, both parties are obligated to comply with the requirements of the the *Guidelines on a Medical Devices Vigilance System according to Articles 83-86 MDR*.
   Both parties shall be as far as possible to carry out an assessment of medical device accidents together with the Competent Authorities.
   Party B is obliged to immediately convey to Party A the information of the accidents, when Party B is informed by the Competent Authorities.

Party B is obliged to communicate immediately to Party A on the response measures taken or planned by the Competent Authorities of the Member States, when Party B is informed by the Competent Authorities.

当医疗器械发生事故时，双方有义务遵守《警戒系统指南》的要求。
双方应尽可能同主管部门一起对医疗器械事故进行评估。
当主管部门告知乙方时，乙方有义务立即向甲方传达事故的信息。
当主管部门告知乙方时，乙方有义务立即向甲方传达成员国主管部门已采取或计划采取的应对措施的信息。

4. In the event of a serious adverse event (including Serious adverse events during clinical investigation, i.e. in the pre- market phase), both Parties are obligated to fully record all serious adverse events.
Party B shall assist Party A in completing a written report of a serious adverse event, which will be submitted by Party B to the Competent Authorities of the listed Member State.

当发生严重不良事件时（包括临床研究阶段，即上市前不良事件），双方有义务全面记录所有严重不良事件的详情。
乙方应协助甲方完成严重不良事件的书面报告，并由乙方向上市成员国主管部门提交报告。

5. Both Parties shall cooperate in structuring a self-inspection process to enable Party B to verify the ability of Party A to perform obligations under the agreement in order to comply with the EU Member States' Expectations.
For details, see Annex 5 "Self-inspection Procedure".

双方应合作构建自检程序，使乙方能够核实甲方履行协议义务的能力，以符合欧盟成员国的期望。
自检程序详情，见附件 5《自检程序》。

Supplement / 补充条款

1. The term of this agreement is __5__ year(s). The fee is__/__ per year.
The term of this Agreement shall be no less than the term of the CE Certificate.

本协议有效期限为 __5__ 年，每年费用为___元。
本协议的有效期应不小于 CE 证书的有效期。

2. During the term of the agreement, if changes such as amendments or upgrades to relevant laws and regulations are made, the new version will be applied and the parties will not enter into a new agreement.

在协议的有效期限内，涉及相关法规修正或升级等变更的，按照新颁布的版本内容执行，双方不再签订新的协议。

3. During the term of the agreement, the parties enter into a supplemental agreement for the additional devices and the parties do not enter into a new agreement.
For details, see Annex 6 "Supplementary Agreements".

在协议的有效期限内，双方针对新增的器械签订补充协议，双方不再签订新的协议。

4. The Agreement shall automatically terminate and expire when:
(1) Without proper reasons, Party A fails to submit the relevant information of the device in time.
(2) Without proper reasons, Party A fails to pay the agreement fee in time.
(3) Party A's CE product certificate is invalid.

当发生下列情况时，协议自动终止并失效：
(1) 无正当理由，甲方未及时提交器械的相关信息。
(2) 无正当理由，甲方未及时缴纳协议费用。
(3) 甲方的CE产品证书失效。

5. Both parties are under an obligation of confidentiality with respect to commercial information involved in the cooperation and may not use it for any purpose other than those covered by the agreement. Not to be disclosed.
对合作涉及的商业信息，双方均负有保密义务，不得用于协议范围以外的任何其他用途，不得泄露。

Annex / 附件

Annex 1 "Description of Operations"	附件 1 《业务说明》
Annex 2 "Information of Device"	附件 2 《器械信息》
Annex 3 "Information List"	附件 3 《信息清单》
Annex 4 "Emergency contact"	附件 4 《紧急联系人》
Annex 5 "Self-inspection Procedure"	附件 5 《自检程序》

Party A: Hefei Hanchin Medical Supplies Co.,Ltd

Add: No.5 Wenwu Road Shuangfeng economic and technological development zone Hefei China

Signature / 签字:

Date / 日期: 2020.9.25

Party B: LiKing GmbH

-

Add: Fraunhofer StraBe 7, 04178 Leipzig

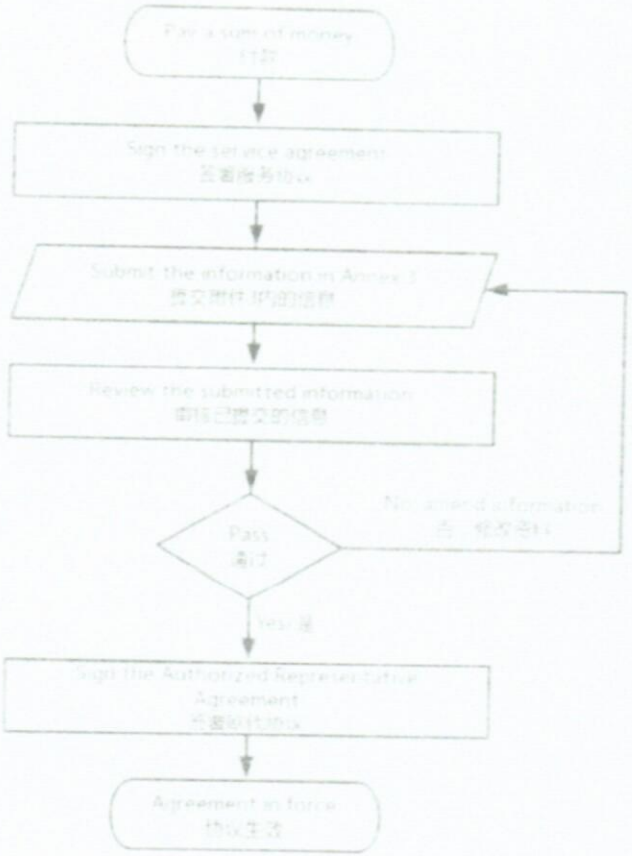
Signature / 签字:

Date / 日期:

LIKING GmbH
(Autorisiert bei SPICA)
Fraunhofer StraBe 7, 04178 Leipzig
Nummer der Firma: HRB 29814
Spica.nx@gmail.com

Annex 1 "Description of Operations" / 附件 1 《业务说明》

1) Description of operations about the authorized representative / 授权代表业务流程



2) Party A shall submit the devices information within 30 days after payment. For details of the information, see Annex 3 "information list".

甲方应在付款后 30 天内，提交器械的信息。信息的相关详情，见附件 3《信息清单》。

3) In some Member States, the Competent Authorities impose mandatory registration requirements for listed devices. In such cases, Party A is obliged to assist Party B to complete the registration of the authorized devices. This agreement does not cover the operation of devices registration. For details, please contact Shanghai Spica Management Consulting Co., Ltd.

在部分成员国内，主管部门施行对上市器械强制注册的要求。这种情况下，甲方有义务协助乙方完成对授权器械的注册。本协议不包含器械注册业务。

Annex 2 "Devices List" / 附件 2 《器械清单》

Devices List / 器械清单				
No.	Proprietary Name of devices / 器械专有名	GMDN	Model / 型号	Class / 类别
1	Sterilization Pouch 灭菌袋			
2	Dental Bibs 牙科垫			
3	Chemical Indicator strip 化学指示卡			
4	Sterilization Wrap 皱纹纸			
5	Indicator Tape 变色指示胶带			

Annex 3 "Information List" / 附件 3 《信息清单》

1) Information List / 信息清单

Information List / 信息清单		
No.	Documents	文件
1	Declaration of conformity	符合性声明
2	Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed)	标签、包装和使用说明副本（符合产品销售所在国家要求的所有语言）
3	Notified Body certification (where relevant)	公告机构认证（如相关）
4	Post market surveillance process and data, vigilance reports and complaints, processes and data	上市后监督流程和数据、警戒报告和投诉、流程和数据
5	Technical documentation relevant to market surveillance investigation being undertaken by the Member State	与成员国正在进行的市场监督调查有关的技术文件
6	Relevant clinical data / notification	相关临床数据/通知
7	Details of any distributors / suppliers putting the CE marked devices on the market	在市场上销售带有 CE 标志的设备的任何经销商/供应商的详细信息
8	Incident reports and corrective actions taken	事件报告和采取的纠正措施
9	Trademark name, Brand name and corresponding model	器械的商标名、品名、对应型号
10	Classification and rules for classification	器械的分类以及分类规则
11	Checklist of basic requirements	基本要求检查表
12	Brief description of devices	器械的简要说明
13	Regulatory requirements and standards for devices (harmonized standards)	器械的法规要求以及标准（协调标准）
14	Introduction to the tests and experiments	有关的检测及实验的介绍
15	Risk management documentation	风险管理文档
16	Compilation of clinical information , evaluation of advantages and disadvantages	临床资料汇编以及利弊评估
17	Alert system	警戒系统
18	Test report	检测报告
19	Production process descriptions, production flowcharts, special process descriptions, key control points, etc.	生产过程描述、生产流程图、特殊过程描述、关键控制点等
20	Sales records	销售记录
21	Documented information on the system operation	体系运行的成文信息

2) For the information in list, Party A shall provide Party B with electronic documents in both English and Chinese. PDF, WORD, JPG, TXT, any of these formats will be sufficient. If relevant information is updated, Party A shall provide Party B with the latest version of the electronic document in a timely manner.

对于清单内的信息，甲方应向乙方提供中英文电子文档，PDF、WORD、JPG、TXT 格式中任何一种即可。相关信息如有更新，甲方应及时向乙方提供最新版本的电子文档。

3) For the devices covered by this agreement, both parties are obliged to keep the information in list, until 5 years after the last device has been manufactured.

For implantable devices covered by this agreement, both parties are obliged to keep the information in list, until 15 years after the last device has been manufactured.

对于本协议涉及的器械，双方有义务保存清单内的信息，直至最后一台器械制造结束的 5 年以后。对于本协议涉及的植入型器械，双方有义务保存清单内的信息，直至最后一台器械制造结束的 15 年以后。

4) The information that Party A shall provide includes, but is not limited to, the information set out below. In response to a reasonable request for information from the Competent Authorities of the Member State, Party A shall provide Party B with the requested information in a timely manner.

For the management approach of the information in list for market surveillance purposes, please refer to Annex 7, "Self-checking procedures".

甲方应提供的信息包括但不限于下列信息。对于成员国主管部门提出的合理的信息要求，甲方应及时向乙方提供被要求的信息。

对于以市场监督为目的的相关信息的管理办法，请参照，附件 5《自检程序》。

5) Party A is obliged to ensure that the information submitted is accurate. In the event that the information submitted by the Party A is incorrect, Party B shall promptly make corrections and assume all liability arising from such situation.

甲方有义务确保提交的信息准确无误。若甲方提交的信息存在错误，甲方应及时进行修正，并承担此错误引起的一切责任。

Annex 4 "Emergency contact" / 附件 4 《紧急联系人》

Party A:

Emergency contact:_____

Tel:_____

Fax:_____

E-mail:_____

Postal Address:_____

Party B:

Emergency contact:_____

Tel:_____

Fax:_____

E-mail:_____

Postal Address:_____

In the event that either Party A or Party B makes any changes, adjustments or cancellations to any information of the above emergency contacts ,The Other Party must be notified promptly in writing or by mail.

If one Party's information cannot be transmitted to the other Party due to a lack of timely notice, the Non-notifying Party will assume all liability arising from this situation.

对于上述紧急联系人的信息，甲、乙双方中的任何一方一旦对任何信息做出任何修改、调整或取消，应书面或邮件方式及时通知对方。

因未及时通知而造成一方的信息无法转达给另一方的，将由未通知方承担此情况引起的一切责任。

Annex 5 "Self-inspection Procedure" / 附件 5 《自检程序》

1) Management procedure of sales records / 销售记录管理程序

Purpose: Enhancing your role in both market surveillance and post-market surveillance

Management method of sales records:

I. During the term of the Agreement, Party A shall periodically submit to Party B all records of sales of authorized devices in the listed Member State.

II. By the last working day of July of each year, Party A shall submit to Party B all sales lists of authorized devices for the period from 1 January to 30 June of the current year; by the last working day of January of each year, Party A shall submit to Party B all sales lists of authorized devices for the period from 1 July to 30 December of the previous year.

III. If the authorized device is not sold in the market of the listed Member State within the specified time period, Party A shall submit to Party B a zero-declaration for the authorized device.

IV Party A is obliged to ensure that the sales records submitted are accurate. In the event that the sales records submitted by Party A are incorrect, Party A shall promptly correct the error and assume all liability arising from such situation.

V. Party B is obliged to keep the records of sales that Party A has submitted as required by the Agreement.

Basis for the procedure: The *Guideline for Authorised Representatives in Article 2(32)MDR in the EU for all medical devices as listed in Appendix A*, the *Guidelines on a Medical Devices Vigilance System according to Articles 83-86 MDR* and this Agreement.

目的：增强乙方在市场监督和上市后监管这两方面起到的作用

销售记录管理方法：

I. 协议有效期内，甲方应定期向乙方提交授权器械在上市成员国的所有销售记录。

II. 每年7月的最后一个工作日前，甲方应向乙方提交本年度1月1日至6月30日的授权器械的所有销售记录；每年1月的最后一个工作日前，甲方应向乙方提交上年度7月1日至12月30日的授权器

域的所有销售清单。

II. 如果规定时间段内，授权器械没有在上市成员国市场售出，甲方应向乙方提交授权器械的零申报声明。

III. 甲方有义务确保提交的销售记录准确无误。若甲方提交的销售记录存在错误，甲方应及时进行修正，并承担此情况引起的一切责任。

IV. 乙方有义务按照协议的要求保存甲方已提交的销售记录。

程序依据：《警戒系统指南》、《授权代表指南》以及本协议相关内容。

2) **Verification procedures for the system operation / 体系运行核实程序**

Purpose: Enable Party B to verify Party A's ability to perform obligations under the Agreement on an ongoing basis

Verification method for the system operation:

I. During the term of the Agreement, Party A shall periodically submit to Party B some documented information on the system operation of authorized devices.

Basis for the procedure: The *Guideline for Authorised Representatives in Article 2(32)MDR in the EU for all medical devices as listed in Appendix A* the *Guidelines on a Medical Devices Vigilance System according to Articles 83-86 MDR* and this Agreement.

目的：使乙方能够持续核实甲方履行协议义务的能力

体系运行核实方法：

I. 协议有效期内，甲方应定期向乙方提交授权器械的体系运行的部分成文信息。

程序依据：《授权代表指南》以及本协议相关内容。

Certification

High Hope Int'l Group Medicines & Health products imp/exp is an authorized seller in Europe for "Perfection" brand products of Hefei Hanchin Medical Supplies Co.,Ltd （Original name： Hefei Telijie Packaging Technology Co.,Ltd）

Products: "Perfection" brand Sterilization Pouch

Hereby to certify

Hefei Hanchin Medical Supplies Co.,Ltd.
Company Stamp:
Signature:

Hefei Telijie Packaging Technology Co.,Ltd.
Company Stamp:
Signature: