

证书第1

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广东外办



双认证 2400006688

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先健科技(深圳)有限公司  
深圳国立商事认证中心

# 证明书

## CERTIFICATE



中国国际贸易促进委员会  
中国国际商会

China Council for the Promotion of International Trade  
China Chamber of International Commerce

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# 中国国际贸易促进委员会 中国国际商会



China Council for the Promotion of International Trade  
China Chamber of International Commerce

## 证明书

CERTIFICATE



号码 No. 244403A0/015906

兹证明：在所附第粤食药监械出20240325号医疗器械产品出口  
销售证明上的广东省药品监督管理局的印章属实。

THIS IS TO CERTIFY THAT: the seal of GUANGDONG MEDICAL  
PRODUCTS ADMINISTRATION on the CERTIFICATE FOR  
EXPORTATION OF MEDICAL PRODUCTS NO. YSYJXC 20240325 is  
genuine.

China Council for the Promotion  
of International Trade



授权签字:

Authorized Signature: Zhou Siyuan

日期: 2024年03月22日  
(Date: Mar. 22, 2024)



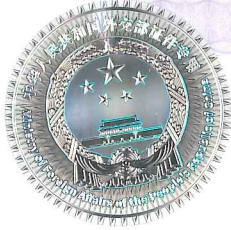
认字第244400013169号

兹证明前面文书上 **中国国际贸易促进委员会(24)** 印章和授权签字人 **周思苑** 的签字属实。



中华人民共和国外交部(440)  
二〇二四年三月二十七日 广州

蔡坚涛



**CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

- 1. Quốc gia ..... **CHXHCN Việt Nam** .....  
Country .....  
Giấy tờ, tài liệu này  
This public document
  - 2. do Ông (Bà) ..... **Sái Kiên Thuận** ..... Ký  
has been signed by
  - 3. với chức danh ..... **Phó Phòng Lãnh sự** .....  
acting in the capacity of
  - 4. và con dấu của ..... **Sở Ngoại vụ tỉnh Quảng Đông** .....  
bears the seal/stamp of  
..... **Trung Quốc** .....
- được chứng nhận / hợp pháp hóa lãnh sự  
Certified
- 5. tại ..... **Quảng Châu** ..... 6. ngày .. **29/03/2024** ..  
at the
  - 7. Cơ quan cấp ..... **TLSQ Việt Nam tại Quảng Châu** .....  
by
  - 8. Số ..... **945/2024** ..  
Nº

Ký tên và đóng dấu  
Signature and seal/stamp

Lãnh sự

**Hoàng Lê Thủy**



中华人民共和国  
PEOPLE'S REPUBLIC OF CHINA  
医疗器械产品出口销售证明  
CERTIFICATE FOR EXPORTATION OF MEDICAL  
PRODUCTS

证书编号：粤食药监械出 20240325 号  
Certificate NO.: 粤食药监械出 20240325 号

产品名称：见附页  
Product(s): See Attachment

规格型号：见附页  
Model: See Attachment

产品注册或备案凭证号：见附页  
Registration certificate(s): See Attachment

生产企业：先健科技（深圳）有限公司  
Manufacturer: Lifetech Scientific(Shenzhen) Co., Ltd.

生产企业住所：深圳市南山区粤海街道高新区社区科技南十二路 22 号先健科技大厦  
8 层  
Address of manufacturer: 8F, LifeTech Scientific Building, No.22, Keji 12th Road South, High-tech Industrial Park,  
Yuehai Subdistrict, Nanshan District, Shenzhen 518063, P. R. China.

生产许可或备案凭证号：粤食药监械生产许 20000028 号  
Manufacturing License(s): 粤食药监械生产许 20000028 号

兹证明上述产品已准许在中国生产和销售。  
This is to certify that the above products have been registered to be  
manufactured and sold in China.

证明有效日期至：2024 年 12 月 18 日  
This certification valid until: 18/12/2024

备注：/  
Remark:



# 医疗器械产品出口销售证明书附页

## ATTACHMENT OF CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号 Certificate No.: 粤食药监械出20240325号



序号 SN	产品名称 Product (s)	规格型号 Model	注册证号 Registration certificate(s)
1	动脉导管未闭封堵器 HeartR PDA Occluder	XJFD0406;XJFD0608;XJFD0810;XJFD1012;XJFD1214;XJFD1416;XJFD1618 XJFD0406;XJFD0608;XJFD0810;XJFD1012;XJFD1214;XJFD1416;XJFD1618	国械注准 20153131360
2	房间隔缺损封堵器 HeartR VSD Occluder	XJFVM04;XJFVM05;XJFVM06;XJFVM07;XJFVM08;XJFVM09;XJFVM10 XJFVM11;XJFVM12;XJFVM13;XJFVM14;XJFVM15;XJFVM16; XJFVJ04;XJFVJ05;XJFVJ06;XJFVJ07; XJFVJ08;XJFVJ09;XJFVJ10 XJFVJ11;XJFVJ12 XJFVJ13;XJFVJ14;XJFVJ15;XJFVJ16 ;XJFVJ17; XJFVJ18 XJFVM04;XJFVM05;XJFVM06;XJFVM07;XJFVM08;XJFVM09;XJFVM10 XJFVM11;XJFVM12;XJFVM13;XJFVM14;XJFVM15;XJFVM16; XJFVJ04;XJFVJ05;XJFVJ06;XJFVJ07; ;XJFVJ08;XJFVJ09;XJFVJ10 XJFVJ11;XJFVJ12 XJFVJ13;XJFVJ14;XJFVJ15;XJFVJ16 ;XJFVJ17; XJFVJ18	国械注准 20163130339
3	房间隔缺损封堵器 HeartR ASD Occluder	XJFS08;XJFS10;XJFS12;XJFS14;XJFS16;XJFS18;XJFS20;XJFS22; XJFS24;XJFS26;XJFS28;XJFS30;XJFS32;XJFS34;XJFS36;XJFS38; XJFS40 XJFS08;XJFS10;XJFS12;XJFS14;XJFS16;XJFS18;XJFS20;XJFS22; XJFS24;XJFS26;XJFS28;XJFS30;XJFS32;XJFS34;XJFS36;XJFS38; XJFS40	国械注准 20163130336
4	输送鞘 SteerEase Introducer	输送鞘管; 扩张器; 装载器; 止血阀; 输送钢缆; SLA5F; SLA6F; SLA7F; SLA8F; SLA9F; SLA10F; SLA11F; SLA12F; SLA13F; SLA14F. SLP5F; SLP6F; SLP7F; SLP8F; SLP9F; SLP10F; SLP11F; SLP12F; SLP13F; SLP14F. SFA5F; SFA6F; SFA7F; SFA8F; SFA9F; SFA10F; SFA11F; SFA12F; SFA13F; SFA14F. SFP5F; SFP6F; SFP7F; SFP8F;	国械注准 20193031790

记录  
CA7  
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(24)  
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序号 SN	产品名称 Product (s)	规格型号 Model	注册证号 Registration certificate(s)
		<p>SFP9F; SFP10F; SFP11F; SFP12F; SFP13F; SFP14F; 输送鞘管; 扩张器; 装载器; 止血 阀; SLAQ5F; SLAQ6F; SLAQ7F; SLAQ8F; SLAQ9F; SLAQ10F; SLAQ11F; SLAQ12F; SLAQ13F; SLAQ14F; SLPQ5F; SLPQ6F; SLPQ7F; SLPQ8F; SLPQ9F; SLPQ10F; SLPQ11F; SLPQ12F; SLPQ13F; SLPQ14F. SFAQ5F; SFAQ6F; SFAQ7F; SFAQ8F; SFAQ9F; SFAQ10F; SFAQ11F; SFAQ12F; SFAQ13F; SFAQ14F. SFPQ5F; SFPQ6F; SFPQ7F; SFPQ8F; SFPQ9F; SFPQ10F; SFPQ11F; SFPQ12F; SFPQ13F; SFPQ14F. 输送鞘管; 扩张器: SFAH5F; SFAH6F; SFAH7F; SFAH8F; SFAH9F; SFAH10F; SFAH11F; SFAH12F; SFAH13F; SFAH14F. SFZH5F; SFZH6F; SFZH7F; SFZH8F; SFZH9F; SFZH10F; SFZH11F; SFZH12F; SFZH13F; SFZH14F. 输送鞘管; 扩张器; 装载器; 输送钢 缆; 穿刺导丝: SFZW5F; SFZW6F; SFZW7F; SFZW8F; SFZW9F; SFZW10F; SFZW11F; SFZW12F; SFZW13F; SFZW14F. 输送钢缆: SFG5F; SFG6F; SFGW5F; SFGW6F.</p> <p>Sheath, Dilator, Loader, Haemostatic Valve, Delivery Cable: SLA5F; SLA6F; SLA7F; SLA8F; SLA9F; SLA10F; SLA11F; SLA12F; SLA13F; SLA14F. SLP5F; SLP6F; SLP7F; SLP8F; SLP9F; SLP10F; SLP11F; SLP12F; SLP13F; SLP14F. SFA5F; SFA6F; SFA7F; SFA8F; SFA9F; SFA10F; SFA11F; SFA12F; SFA13F; SFA14F. SFP5F; SFP6F; SFP7F; SFP8F; SFP9F; SFP10F; SFP11F; SFP12F; SFP13F; SFP14F. Sheath, Dilator, Loader, Haemostatic Valve: SLAQ5F; SLAQ6F; SLAQ7F; SLAQ8F; SLAQ9F; SLAQ10F; SLAQ11F; SLAQ12F; SLAQ13F; SLAQ14F.</p>	



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序号 SN	产品名称 Product (s)	规格型号 Model	注册证号 Registration certificate(s)
		<p>SLPQ5F; SLPQ6F; SLPQ7F; SLPQ8F; SLPQ9F; SLPQ10F; SLPQ11F; SLPQ12F; SLPQ13F; SLPQ14F.</p> <p>SFAQ5F; SFAQ6F; SFAQ7F; SFAQ8F; SFAQ9F; SFAQ10F; SFAQ11F; SFAQ12F; SFAQ13F; SFAQ14F.</p> <p>SFPQ5F; SFPQ6F; SFPQ7F; SFPQ8F; SFPQ9F; SFPQ10F; SFPQ11F; SFPQ12F; SFPQ13F; SFPQ14F.</p> <p>Sheath, Dilator:</p> <p>SFAH5F; SFAH6F; SFAH7F; SFAH8F; SFAH9F; SFAH10F; SFAH11F; SFAH12F; SFAH13F; SFAH14F.</p> <p>SFZH5F; SFZH6F; SFZH7F; SFZH8F; SFZH9F; SFZH10F; SFZH11F; SFZH12F; SFZH13F; SFZH14F.</p> <p>Sheath, Dilator, Loader, Delivery Cable, Guide Wire:</p> <p>SFZW5F; SFZW6F; SFZW7F; SFZW8F; SFZW9F; SFZW10F; SFZW11F; SFZW12F; SFZW13F; SFZW14F.</p> <p>Delivery Cable:</p> <p>SFG5F; SFG6F; SFGW5F; SFGW6F.</p>	
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