

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：黑药监械出 20240035
Certificate No.: 黑药监械出 20240035

产品名称：腹腔镜手术系统
Product(s): Surgical System (Endoscopic Instrument Control System with
Instruments and Accessories)

规格型号：SR2000
Model: SR2000

产品注册或备案凭证号：国械注准 20243011275
Registration certificate(s): 国械注准 20243011275

生产企业：哈尔滨思哲睿智能医疗设备股份有限公司
Manufacturer: Harbin Sagebot Intelligent Medical Equipment Co., Ltd.

生产企业住所：哈尔滨经开区哈平路集中区大连北路 8 号
Address of manufacturer: No. 8, Dalian North Road, Concentrated area Haping
Road, Economic Development Zone, Harbin, Heilongjiang Province, People's
Republic of China.

生产许可或备案凭证号：黑药监械生产许 20230003 号
Manufacturing License(s): 黑药监械生产许 20230003 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
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证明有效日期至：2025 年 9 月 19 日
This certification valid until:

备注：
Remark:



附件一

中文 (Chinese version):

产品结构组成附页

序号	系统名称	规格型号	组成部分
1	腹腔内窥镜手术系统	SR2000	医生控制台 (可选配第 2 个)、患者手术平台、台车、手术器械和附件组成。其中手术器械包括无源手术器械和高温手术器械,附件包括腹部穿刺器、腹腔镜接口件和可拆卸线缆。
序号	设备名称	规格型号	组成部分
1	医生控制台	SC2000	辅助显示屏 (上)、左扶手屏、右扶手屏、个性化设置面板、触控板、扶手、脚踏开关面板、显示器立柱、背包、辅助显示屏 (下)、主手、制动踏板、底座、主显示屏 (3D, 分辨率不低于 1080P) 辅助显示屏 (左/右) (选配)
2	患者手术平台	PC2000	底盘、把手、大立柱、后横梁、前横梁、转盘、小横梁、小立柱、肘部杆、冗余臂、旋转臂、立臂、横臂、滑台、患者手术平台操作手柄、触控屏
3	台车	VC2000	台车主体、电气仓、系统信息显示屏、助手屏 (3D, 分辨率不低于 1080P)
可拆卸线缆			
序号	名称	型号	
1	10A 电源线	W01250P	/
2	16A 电源线	W01256P	
3	视频传输线	W01252S	
4	视频传输线	W01268S	
5	通讯线	W01253M	
6	通讯线	W01254M	
无源手术器械			
序号	名称	型号	配置
1	大号持针钳	200194	标配
2	小号持针钳	200006	
3	直双窗无创抓钳	200189	选配
4	弯双窗无创抓钳	200347	
5	直单窗有创抓钳	200093	
6	直单窗无创抓钳	200049	
7	弯分离钳	200345	
高频手术器械			
序号	名称	型号	配置

1	单极弯剪刀	200179	标配
2	单极小号电钩	200183	
3	双极马里兰钳	200172	
4	平头窗式双极钳	200205	
5	单极直剪刀	200007	选配
6	单极大号电钩	200185	
7	微无创平头窗式双极钳	200206	

重复性使用腹部穿刺器

序号	名称	型号	配置	产品组成	型号
1	穿刺器	A2003	标配	穿刺套	200002
				穿刺针	200008
				8mm 套管密封帽	150077
2	穿刺器	A2001	选配	穿刺套	200002
				无刃穿刺针	200359
				8mm 套管密封帽	150077
3	穿刺器	A2002	选配	穿刺套	200002
				无刃穿刺针	200359
				5-8mm 套管密封帽	150361
4	穿刺器	A2004	选配	穿刺套	200002
				穿刺针	200008
				5-8mm 套管密封帽	150361
5	穿刺器	A2005	选配	穿刺套-长	200004
				无刃穿刺针-长	200360
				8mm 套管密封帽	150077
6	穿刺器	A2006	选配	穿刺套-长	200004
				无刃穿刺针-长	200360
				5-8mm 套管密封帽	150361
7	穿刺器	A2007	选配	穿刺套-长	200004
				穿刺针-长	200009
				8mm 套管密封帽	150077
8	穿刺器	A2008	选配	穿刺套-长	200004
				穿刺针-长	200009
				5-8mm 套管密封帽	150361

腹腔镜接口件

序号	名称	型号
1	腹腔镜接口件 A	200028
2	腹腔镜接口件 B	200029

英文 (English version):

Appendix: Product Structure

No.	Item Name	Specification/Model	Component(s)
1	Surgical System (Endoscopic Instrument Control System with Instruments and Accessories)	SR2000	The Surgical System consist of Surgeon Console(2nd Surgeon Console for Optional), Patient Cart, Vision Cart, Surgical instrument and accessories. The surgical instruments included passive surgical instruments and high-frequency surgical instruments, and the accessories included abdominal puncture instruments (Trocar), Laparoscope Coupler, and Detachable Cables.
1	Surgeon Console	SC2000	Auxiliary display (top), left handrail screen, right handrail screen, personalized setting panel, touch pad, handrail, foot switch panel, display column, backpack, auxiliary display (bottom), main hand, brake pedal, base, main display (3D, resolution not less than 1080P) Auxiliary display (left/right) (optional)
2	Patient Cart	PC2000	Chassis, handles, large column, rear crossbeam, front crossbeam, turntable, small crossbeam, small column, elbow bar, redundant arm, swivel arm, vertical arm, horizontal arm, sliding table, Patient cart operating handle, touch screen.
3	Vision Cart	VC2000	Main body of Vision Cart, electrical compartment, system information display, assistant screen (3D, resolution not less than 1080P)

Detachable Cables

No.	Item Name	Specification/Model	
1	10A Power Line	W01250P	/
2	16A Power Line	W01256P	
3	Video Transmission Line	W01252S	
4	Video Transmission Line	W01268S	
5	Communication Line	W01253M	
6	Communication Line	W01254M	

Passive Surgical Instruments

No.	Item Name	Specification/Model	Configuration
1	Large Needle Driver	200194	Standard
2	Small Needle Driver	200006	
3	Double Fenestrated Grasper	200189	Optional
4	Tip-Up Double Fenestrated Grasper	200347	
5	Fenestrated Forceps	200093	
6	Cadiere Forceps	200049	
7	Curved Dissector	200345	

High-Frequency Surgical Instruments			
No.	Item Name	Specification/Model	Configuration
1	Monopolar Curved Scissors	200179	Standard
2	Small Permanent Cautery Hook	200183	
3	Maryland Bipolar Forceps	200172	
4	Fenestrated Bipolar Forceps	200205	
5	Monopolar Straighten Scissors	200007	Optional
6	Large Permanent Cautery Hook	200185	
7	Mini Noninvasive Round Tip Fenestrated Bipolar Forceps	200206	

Reusable Abdominal Puncture Instruments(Trocar)

No.	Item Name	Specification/Model	Configuration	Components	Specification/Model
1	Trocar	A2003	Standard	Puncture Set	200002
				Puncture Needle	200008
				8mm Cannula Seal	150077
2	Trocar	A2001	Optional	Puncture Set	200002
				Bladeless Puncture Needle	200359
				8mm Cannula Seal	150077
3	Trocar	A2002	Optional	Puncture Set	200002
				Bladeless Puncture Needle	200359
				5-8mm Cannula Seal	150361
4	Trocar	A2004	Optional	Puncture Set	200002
				Puncture Needle	200008
				5-8mm Cannula Seal	150361
5	Trocar	A2005	Optional	Puncture Set - long	200004
				Bladeless Puncture Needle - long	200360
				8mm Cannula Seal	150077
6	Trocar	A2006	Optional	Puncture Set- long	200004
				Bladeless Puncture Needle - long	200360
				5-8mm Cannula Seal	150361
7	Trocar	A2007	Optional	Puncture Set - long	200004
				Puncture Needle-long	200009
				8mm Cannula Seal	150077
8	Trocar	A2008	Optional	Puncture Set -long	200004
				Puncture Needle-long	200009
				5-8mm Cannula Seal	150361

Laparoscope Coupler

No.	Item Name	Specification/Model
1	Laparoscope Coupler A	200028
2	Laparoscope Coupler B	200029

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证书编号: 黑药监械出 20240036
Certificate NO.: 黑药监械出 20240036

产品名称: 一次性使用无菌保护罩
Product(s): Disposable Sterile Drape

规格型号: 150015: 295cm × 80cm (器械臂保护罩); 150279: 295cm × 80cm (持镜臂保护罩);
150341: 200cm × 180cm (立柱保护罩); 200015: 300cm × 50cm (机械臂保护罩)
Model: 150015: 295cm × 80cm (Disposable Sterile Instrument Arm Drape); 150279: 295cm
× 80cm (Disposable Sterile Camera Arm Drape); 150341: 200cm × 180cm (Disposable
Sterile Column Drape); 200015: 300cm × 50cm (Disposable Sterile Robotic Arm Drape)

产品注册或备案凭证号: 黑械注准 20232140082
Registration certificate(s): 黑械注准 20232140082

生产企业: 哈尔滨思哲睿智能医疗设备股份有限公司; 苏州康多机器人有限公司
Manufacturer: Harbin Sagebot Intelligent Medical Equipment Co., Ltd.; Suzhou Kangduo
Robot Co., Ltd.

生产企业住所: 苏州高新区青城山路 300 号工业村标准厂房 2 号厂房 (委托生产); 哈尔滨经
开区哈平路集中区大连北路 8 号 (成品库房)
Address of manufacturer: Building 2 Standard Plant, Industrial Village, No. 300
Qingchengshan Road, Suzhou New District, Suzhou, Jiangsu Province, People's Republic
of China. (Entrusted manufacture); No. 8, Dalian North Road, Concentrated area Haping
Road, Economic Development Zone, Harbin, Heilongjiang Province, People's Republic
of China. (Products warehouse)

生产许可或备案凭证号: 黑药监械生产许 20230003 号; 苏药监械生产许 20210079 号
Manufacturing License(s): 黑药监械生产许 20230003 号; 苏药监械生产许 20210079 号

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备注: 受托生产企业: 苏州康多机器人有限公司 (统一社会信用代码证号:
9132050508934890XP)
Remark: Manufacturer entrusted with production: Suzhou Kangduo Robot Co., Ltd.
(USCI: 9132050508934890XP)



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证书编号: 黑药监械出 20240037
Certificate NO.: 黑药监械出 20240037

产品名称: 一次性使用能量器械护套
Product(s): Tip Cover Accessory

规格型号: 150180
Model: 150180

产品注册或备案凭证号: 黑械注准 20232010085
Registration certificate(s): 黑械注准 20232010085

生产企业: 哈尔滨思哲睿智能医疗设备股份有限公司; 苏州康多机器人有限公司
Manufacturer: Harbin Sagebot Intelligent Medical Equipment Co., Ltd.; Suzhou Kangduo Robot Co., Ltd.

生产企业住所: 苏州高新区青城山路 300 号工业村标准厂房 2 号厂房 (委托生产); 哈尔滨
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