



中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械出口销售证明(I)
CERTIFICATE FOR EXPORTATION OF MEDICAL DEVICE

证书编号 Certificate No.		苏药监械出2026000444号 No.MDJS2026000444
产品名称 Product Name		见附件 See Attachment
型号规格 Model and Specification		见附件 See Attachment
注册证编号或者产品备案编号 Medical Device Registration No. / Medical Device Filing No.		见附件 See Attachment
医疗器械注册人 或者备案人 Medical Device Registrant or Medical Device Filing Entity	名称 Enterprise Name	苏州神韵医疗器械有限公司 Suzhou Shenyun Medical Equipment Co., Ltd.
	住所 Domicile	苏州市吴中区临湖镇银藏路 666 号 11 幢 Building 11, No. 666 Yinzang Road, Linhu Town, Wuzhong District, Suzhou City
生产企业 Medical Device Manufacturer	名称 Enterprise Name	苏州神韵医疗器械有限公司 Suzhou Shenyun Medical Equipment Co., Ltd.
	住所 Domicile	苏州市吴中区临湖镇银藏路666号11幢 Building 11, No. 666 Yinzang Road, Linhu Town, Wuzhong District, Suzhou City
		生产地址 Manufacturing Address
	生产许可证编号 或者生产备案编 号 Medical Device Manufacturing License No./Manufacturin g Filing No.	苏药监械生产许20230280号
		苏药监械生产许 20230280号
兹证明上述医疗器械已准许在中国境内生产和销售。 This is to certify that the above medical device(s) have been approved for manufacture and sale in China. 出具出口销售证明作为服务事项提供给中国境内医疗器械注册人或者备案人。出具出口销售证 明时，出具证明的部门未评估或者验证产品是否符合进口国家（地区）的要求，申请人有责任确 遵守进口国家（地区）的相关要求。 The Certificate for Exportation is issued as a service item to the Medical Device Registration		



Certificates or Filing Entities in China. The applicants are obligated to comply with the requirements of the importing countries(regions), as the certifying authority does not evaluate or verify if the products comply with the requirements of the importing countries(regions) when issuing the Certificate for Exportation.

*如医疗器械注册证或者产品备案、医疗器械生产许可证或者生产备案被依法吊销、撤销、注销或者取消的，本证明自吊销、撤销、注销或者取消之日起失效。

*If the Medical Device Registration Certificate, Medical Device Filing Certificate/Filing Number Notification, or the Medical Device Manufacturing License/Filing Certificate is revoked, withdrawn, de-registered or canceled according to law, this Certificate for Exportation shall become invalid from the date of such revocation, withdrawal, de-registration or cancellation.

证明有效日期至 This Certificate Remains Valid Until	2028年11月01日 2028/11/01
备注 Remark	
出具证明的部门 Certifying authority	江苏省药品监督管理局 Jiangsu Medical Products Administration 2026年07月16日 2026/07/16 (盖章 Stamp)



证书编号：苏药监械出 2026000444 号

Certificate NO.: No.MDJS2026000444

序号 NO	产品名称 (中文) Product(s) (chinese)	产品名称 (英文) Product(s)	规格型号 (中文) Specification/model (c hinese)	规格型号 (英文) Specification/mode	产品注册证 或备案凭证 号(中文) Registration certificate(s)	产品注册证 或备案凭证 号(英文) Registration certificate(s)
1	一次性腹壁缝合器套件	Sterile Single Use Fascial Closure System	见附件 (苏械注准 20252021373)	See Attachment (NO.SXZZ2025 2021373)	苏械注准 20252021373	NO.SXZZ202520 21373
2	一次性使用外科手术引流导管套装	Sterile Single Use Negative Pressure Drainage Set	见附件 (苏械注准 20252141737)	See Attachment (NO.SXZZ2025 2141737)	苏械注准 20252141737	NO.SXZZ202521 41737
3	一次性使用胃管	Gastric calibration tube	32Fr、34Fr、36Fr、38Fr 、40Fr。	32Fr、34Fr、36Fr、38Fr、 40Fr	苏械注准 20232141554	NO.SXZZ202321 41554