

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 (I)

证书编号 Certificate No.		浙药监械出 2026000513 号
		No.MDZJ2026000513
产品名称 Product Name		一次性使用热湿交换器, 见附件 (共 2 页)
		Disposable Heat and Moisture Exchanger (HME).See Attachment(2 Pages)
型号规格 Model and Specification		见附件 (共 2 页)
		See Attachment(2 Pages)
注册证编号或者产品备案编号 Medical Device Registration No. / Medical Device Filing No.		浙械注准 20262080378
		浙械注准 20262080378
医疗器械注册人 或者备案人 Medical Device Registrant or Medical Device Filing Entity	名称 Enterprise Name	绍兴瑞博医疗器械有限公司
		Shaoxing Reborn Medical Devices Co.,Ltd.
	住所 Domicile	浙江省绍兴市越城区海天道 21 号医疗器械科技产业园 6 号楼 1 楼
		1F, Building No.6, Medical Device Industrial Park, No.21 Haitian Road, Yue cheng District, Shaoxing, Zhejiang
生产企业 Medical Device Manufacturer	名称 Enterprise Name	绍兴瑞博医疗器械有限公司
		Shaoxing Reborn Medical Devices Co.,Ltd.
	住所 Domicile	浙江省绍兴市越城区海天道 21 号医疗器械科技产业园 6 号楼 1 楼
		1F, Building No.6, Medical Device Industrial Park, No.21 Haitian Road, Yue cheng District, Shaoxing, Zhejiang
	生产地址 Manufacturing Address	浙江省绍兴市越城区海天道 21 号医疗器械科技产业园 6 号楼 1 楼、3 楼
		1F、3F ,Building No.6, Medical Device Industrial Park, No.21 Haitian Road, Yue cheng District, Shaoxing, Zhejiang
	生产许可证编号 或者生产备案编 号 Medical Device Manufacturing License No./Manufacturing	浙药监械生产许 20220033 号
		浙药监械生产许 20220033 号

	Filing No.	
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，申请人有责任确保遵守进口国家（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Certificate/Filing Number Notification, or the Medical Device Manufacturing License/Filing Certificate is revoked, withdrawn, de-registered or canceled according to law, this Certificate for Exportation shall become invalid from the date of such revocation, withdrawal,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	2027年03月13日 03/13/2027	
备注 Remark	/ /	
出具证明的部门 Certifying Authority	浙江省药品监督管理局 Zhejiang Medical Products Administration 	