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中国国际贸易促进委员会



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

证明书 CERTIFICATE



号码 No. 224403A0/011375

兹证明：在所附第国械注准20213080853号医疗器械注册证上国家药品监督管理局的电子印章属实，其英文译本与中文文本一致。

THIS IS TO CERTIFY THAT: the electronic seal of NATIONAL MEDICAL PRODUCTS ADMINISTRATION on the REGISTRATION CERTIFICATE FOR MEDICAL DEVICE NO. GXZZ 20213080853 is genuine, and the English version of the annexed is true to its Chinese text.



China Council for the Promotion
of International Trade

授权签字:

Authorized
Signature: LIU JUN

日期: 2022年03月08日
(Date: Mar. 08, 2022)

证明书查询网站 for verifying the certificate: <http://www.rzccpit.com/validate.html>

中华人民共和国医疗器械注册证

注册证编号：国械注准20213080853

注册人名称	深圳市安保科技有限公司
注册人住所	深圳市南山区粤海街道高新区社区高新南七道20号深圳国家工程实验室大楼A1302
生产地址	深圳市宝安区石岩街道塘头1号路创维创新谷5#C栋3楼
代理人名称	/
代理人住所	/
产品名称	呼吸机
型号、规格	T6
结构及组成	由主机（包括气路、电子系统、机械结构、显示器、二氧化碳模块）、台车、支撑臂组成。
适用范围	本产品预期在专业医疗机构内部的重症监护环境，或在专业医疗机构内部或院外进行转运时使用。用于对成人、儿童和婴幼儿患者进行通气辅助及呼吸支持。本产品应由经过培训合格的、获得授权的医务人员进行操作。
附件	产品技术要求
其他内容	/
备注	

审批部门：国家药品监督管理局



批准日期：二〇二一年十月二十六日
生效日期：二〇二一年十月二十六日
有效日期：二〇二六年十月二十五日

Medical Device Registration Certificate of the People's Republic of China

Registration Certificate No.: GXZZ20213080853

Name of registrant	Ambulanc (Shenzhen) Tech. Co., Ltd.
Domicile of registrant	A1302, Shenzhen National Engineering Laboratory Building, No. 20 Gaoxinnan 7th Road, High-tech Zone Community, Yuehai Street, Nanshan District, Shenzhen
Production address	3F, Building C, 5#, Skyworth Innovation Industrial Park, Tangtou 1st Road, Shiyan Street, Baoan District, Shenzhen
Name of agent	/
Domicile of agent	/
Product name	Ventilator
Type	T6
Structure and composition	The product is composed of main machine (including gas path, electronic system, mechanical structure, display and carbon dioxide module), trolley and support arm.
Scope of application	This product is intended for use in the intensive care environment of a professional medical institution or for transport inside a professional medical institution or out of hospital. It is used for ventilation assistance and respiratory support for adult, pediatric and infant patients. This product should be operated by trained, qualified and authorized medical personnel.
Appendix	Technical Requirements for Products
Others	/
Remarks	

Approved by: National Medical Products Administration

Approved on: October 26, 2021

Entry-into-force date: October 26, 2021

National Medical Products Administration

Valid until: October 25, 2026

Special seal for medical device registration

