

附件 1

医疗器械召回事件报告表

提交：☒企业所在地省级食品药品监督管理部门☐器械注册/备案部门

产品名称	呼吸湿化治疗仪加热 呼吸管路和配件	注册证或备案 凭证编码	国械注进 20172086326
生产企业名称	费雪派克医疗保健有限公司		
代理人名称	费雪派克医疗保健（广州）有限公司		
召回单位负责人和联系方式，经办人和联系方式	单位负责人-陈磊智-15013022623 经办人-谢信荣-13826141847		
产品的适用范围	产品用于有自主呼吸的患者，设计与费雪派克公司呼吸湿化治疗仪（型号：PT101AZ、PT100AZ）配套使用，为病人输送加温湿化气体。		
涉及地区和国家	中国	召回级别	二级召回
涉及产品生产（或进口中国）批次、数量	288 批次：30367	涉及产品 型号、规格	PT101AZ
识别信息 （如批号）	（见附录）	涉及产品在 中国的销售数量	30367
召回原因简述	本次召回旨在告知客户，为确保呼吸湿化治疗仪在其预期使用寿命内得到妥善维护，现对消毒工具套装说明书进行更新。当呼吸湿化治疗仪意外断开电源时，设备将发出持续至少 120 秒的音频报警。更新后的消毒工具套装说明书增加了定期测试该报警功能的要求，测试应在每次消毒结束后执行。此次更新源于多起境外报警持续时间不足 120 秒的报告，该情况可能延迟用户的觉察和重新连接电源的时间。目前尚未发生与该问题相关的严重伤害或死亡事件。		
纠正行动简述（包括召回要求和处理方式等）	所有呼吸湿化治疗仪的收货方（一级经销商）将收到召回通知及响应表格。该通知将告知客户为确保呼吸湿化治疗仪在其预期使用寿命期间得到妥善维护，需对消毒工具套装说明书进行更新。当设备意外断电时，呼吸湿化治疗仪将发出持续至少 120 秒的音频报警。本次更新的消毒工具套装说明书新增了定期测试该报警功能的要求，测试应在每次消毒结束后执行。费雪派克医疗将通知所有一级经销商关于此项更新，并将新的电子版用户说明书附在通知函一起发送给经销商，并要求其作出回应。在适用的情况下，一级经销商		

	需转告下级收货方。若费雪派克的区域办事处在 15 天内未收到一级经销商的回复，将发送至少三次后续通知及响应要求。
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负责人：（签字）陈磊

报告人：（签字）谢信荣

报告日期：2025年10月9日

附录

涉及的产品批号	
型号规格	批号
PT101AZ	2100307589
PT101AZ	2100310176
PT101AZ	2100312707
PT101AZ	2100335825
PT101AZ	2100343130
PT101AZ	2100344574
PT101AZ	2100351693
PT101AZ	2100357802
PT101AZ	2100367467
PT101AZ	2100373833
PT101AZ	2100379722
PT101AZ	2100405894
PT101AZ	2100409255
PT101AZ	2100414357
PT101AZ	2100420204
PT101AZ	2100423804
PT101AZ	2100428306
PT101AZ	2100433791
PT101AZ	2100439394
PT101AZ	2100451045
PT101AZ	2100456152
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