

医疗器械召回事件报告表

(公司内部召回编号: FMI34139)

提交: ☒ 企业所在地省级药品监督管理部门

☒ 器械注册/备案部门

产品名称	蒸发器	注册证或备案 凭证编码	国械注进 20163082371 国械注进 20193080022
生产企业名称	Datex-Ohmeda, Inc. 德恩欧美达公司		
代理人名称	通用电气医疗系统贸易发展(上海)有限公司		
召回单位负责人和联系方式, 经办人和联系方式	负责人: 李延 010-57388736 经办人: 彭一苇 010-57388736		
产品的适用范围	见 附表 1 产品信息		
涉及地区和国家	中国、美国、欧盟等 国家和地区	召回级别	二级
涉及产品生产(或进口中国)批次、数量	2659 件	涉及产品 型号、规格	Tec 6 Plus、Tec 820 ISO、Tec 820 SEV、 Tec 850 ISO、Tec 850 SEV
识别信息 (如批号)	见 附表 2 识别信息	涉及产品在 中国的销售数量	2659 台
召回原因简述	GE 医疗近期发现, 由于生产问题, 2023 年 4 月~2024 年 10 月期间生产的部分 Tec 6 Plus 和 Tec 800 系列蒸发器输送的麻醉气体浓度可能低于蒸发器刻度盘设定值。如果没有与麻醉气体监测功能一起使用, 可能会导致麻醉效果不足, 从而导致患者在手术过程中移动或出现术中知晓的情况。目前尚未收到由于该问题造成任何患者伤害的报告。维护高标准的安全和质量是我们的首要任务, GE 医疗决定通过主动召回, 免费为受影响客户修正该潜在的产品问题。		
纠正行动简述(包括召回要求和处理方式等)	1. GE 医疗将通知客户此问题和注意事项; 2. GE 医疗将派工程师至客户现场检查确认以及为客户修正此问题(如需要)。 注: 本次纠正行动不涉及受影响产品的停用及退回。		

报告单位: (盖章)

报告人:

负责人:

报告日期:

2025.1.20

附表 1 产品信息

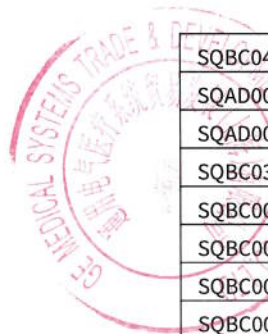
产品名称	型号	医疗器械注册证号	生产企业名称	产品适用范围
蒸发器	Tec 6 Plus	国械注进 20163082371	Datex-Ohmeda, Inc.	本产品为麻醉系统提供浓度可控的麻醉气体。可配套用于 GE 系列的麻醉系统（Aespire 7900, Aespire、Aestiva/5 7100、Aestiva/5 7900、Avance、Avance CS2、Aespire View）。
	Tec 820 ISO、Tec 820 SEV Tec 850 ISO、Tec 850 SEV	国械注进 20193080022		该蒸发器适用于具有 Selectatec™ 系列安装支管的所有通用电气医疗系统（中国）有限公司、General Electric（Datex-Ohmeda, Inc. 即德恩欧美达公司）研发生产的麻醉机及麻醉系统，用于气化挥发吸入性麻醉药物，并通过麻醉机或麻醉系统将吸入性麻醉药物输送到患者呼吸系统，使手术中的患者处于麻醉的状态。

附表 2 识别信息

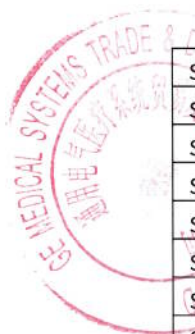
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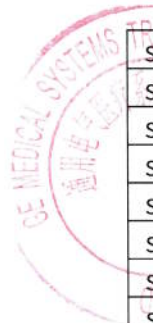
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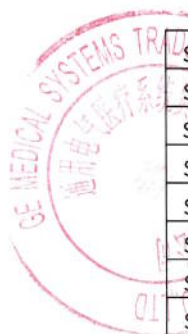
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