

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	主动脉内球囊反搏泵(商品名: CARDIOSAVE) 主动脉内球囊反搏泵	注册证或 备案凭证 编码	国食药监械(进)字 2014第3214542号 国械注进 20193082223
生产企业名称	德塔斯康医疗股份有限公司Datascope Corp.		
召回单位负责人和 联系方式, 经办人 和联系方式	负责人: 胡文仙 联系方式: 021-61973999 经办人: 楼雨晴 联系方式: 021-61973999		
产品的适用范围	该产品临床适用于成人患者, 对主动脉球囊进行充气和排气, 通过反搏原理为左心室提供暂时支持。主动脉球囊放置于下行主动脉, 位于左锁骨动脉分支末端。放置球囊后, 将反搏泵调整为心电图(ECG)或动脉压力波形同步触发, 确保在心动周期的相应位置进行充气和排气。		
涉及地区和国家	中国	召回级别	三级
涉及产品生产(或 进口中国)批次、 数量	804台(其中4台为样机)	涉及产品 型号、规 格	CARDIOSAVE Hybrid
识别信息(如批号)	序列号信息详见附件 UDI: 10607567108421	涉及产品 在中国的 销售数量	800台
召回原因简述	生产企业调查发现, 在中国销售的主动脉内球囊反搏泵(IABP)其软件版本与产品技术要求中的软件版本描述不一致。本着对客户负责的态度, 确保产品使用安全、有效, 企业决定对其进行召回。本次召回仅涉及附件所列型号/序列号产品, 其他型号/序列号产品不受影响。		
纠正行动简述(包 括召回要求和处理 方式等)	1. 识别受影响的客户, 发送召回通知给到受影响的客户。 2. 对受影响设备的软件进行调整, 调整为符合产品技术要求的软件版本。		

报告单位: (盖章)

报告人: (签字)

负责人: (签字)

报告日期:

胡文仙

2024-10-14

受影响序列号:

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