

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Intra-Aortic Balloon Pump	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.		
代理人名称	迈柯唯(上海)医疗设备有限公司		
召回单位负责人和联系方式, 经办人和联系方式	负责人: 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 and 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 and 排气。		
涉及地区和国家	全球	召回级别	二级
涉及产品生产(或进口中国)批次、数量	518台(其中5台样机、1台已返厂)	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	512台
召回原因简述	生产企业对其生产的主动脉内球囊反搏泵(IABP)进行主动纠正, 原因是可能影响IABP性能的六个问题: 电池未预期充电; 心电图信号差或无信号; 自动充气失败报警; 气体泄露和气体增加报警; 系统高温报警; 光纤损坏。		
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. 要求客户遵循产品说明书的要求操作设备。 3. 修订说明书附录, 新增警用户注意事项。		

报告单位: (盖章)

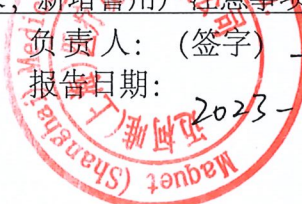
报告人: (签字)

楼雨晴

负责人: (签字)

报告日期:

2023-08-07



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