

医疗器械召回事件报告表

(公司内部召回编号: FMI 23012)

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	X 射线计算机体层摄影设备	注册证或备案凭证编码	国械注准 20173064521、国械注准 20193060525、国械注准 20193061811、国械注准 20203060996
生产企业名称	航卫通用电气医疗系统有限公司		
代理人名称	不适用		
召回单位负责人和联系方式, 经办人和联系方式	孙莹 18101130386		
产品的适用范围	国械注准 20173064521: 该产品适用于常规临床 CT 检查, 支持冠状动脉血管造影扫描。国械注准 20193060525: 产品用于临床 CT 检查, 支持冠状动脉 CT 血管造影扫描。国械注准 20193061811: 该产品适用于临床 CT 检查 (心脏冠脉除外)。国械注准 20203060996: 该产品适用于常规临床 CT 检查, 支持冠脉血管造影成像、能谱成像、放疗模拟定位。		
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	88 台	涉及产品型号、规格	Optima CT 680 Expert、Revolution Ace、Revolution Advance、Revolution CT ES、Revolution Maxima
识别信息 (如批号)	见附表 1	涉及产品在中国的销售数量	88 台
召回原因简述	我司近期发现部分 CT 系统的中文标签上的参考信息有误。维护高标准的安全和质量是我们的首要任务, 我司决定对涉及产品采取主动召回。		
纠正行动简述 (包括召回要求和处理方式等)	1. 我司将发送客户信通知客户此问题; 2. 我司将派工程师至现场对受影响的产品标签进行免费更正。 3. 本次纠正行动不涉及受影响产品的停用及退回。 4. 召回工作中涉及到的民事纠纷问题, 由本公司与医疗器械经营使用单位按民法规定处理。		

报告单位: (盖章)

报告人: 孙莹

负责人: 孙莹

报告日期: 2025 年 5 月 29 日

附表 2 识别信息

识别信息	型号	UDI#	识别信息	型号	UDI#
CBDAG2400012HM	Revolution Ace	01008406821461591124060021CBDAG2400012HM	CBDAG2400028HM	Revolution Ace	01008406821461591124110021CBDAG2400028HM
CBDAG2400013HM	Revolution Ace	01008406821461591124060021CBDAG2400013HM	CBDAG2400029HM	Revolution Ace	01008406821461591124110021CBDAG2400029HM
CBDAG2400014HM	Revolution Ace	01008406821461591124060021CBDAG2400014HM	CBDAG2400030HM	Revolution Ace	01008406821461591124110021CBDAG2400030HM
CBDAG2400015HM	Revolution Ace	01008406821461591124060021CBDAG2400015HM	CBDAG2400031HM	Revolution Ace	01008406821461591124110021CBDAG2400031HM
CBDAG2400016HM	Revolution Ace	01008406821461591124060021CBDAG2400016HM	CBDAG2400032HM	Revolution Ace	01008406821461591124120021CBDAG2400032HM
CBDAG2400017HM	Revolution Ace	01008406821461591124060021CBDAG2400017HM	CBDAG2400033HM	Revolution Ace	01008406821461591124120021CBDAG2400033HM
CBDAG2400018HM	Revolution Ace	01008406821461591124060021CBDAG2400018HM	CBDAG2400034HM	Revolution Ace	01008406821461591124120021CBDAG2400034HM
CBDAG2400019HM	Revolution Ace	01008406821461591124070021CBDAG2400019HM	CBDAG2400035HM	Revolution Ace	01008406821461591124120021CBDAG2400035HM
CBDAG2400020HM	Revolution Ace	01008406821461591124070021CBDAG2400020HM	CBDLG2500001HM	Revolution Advance	01001952783852151125010021CBDLG2500001HM
CBDAG2400021HM	Revolution Ace	01008406821461591124090021CBDAG2400021HM	CBDNG2400006HM	Revolution Maxima	01008406821461801124060021CBDNG2400006HM
CBDAG2400022HM	Revolution Ace	01008406821461591124090021CBDAG2400022HM	CBDNG2400007HM	Revolution Maxima	(01)00840682146180(11)240900(21)CBDNG2400007HM
CBDAG2400023HM	Revolution Ace	01008406821461591124090021CBDAG2400023HM	CBDNG2400010HM	Revolution Maxima	01008406821461801124090021CBDNG2400010HM
CBDAG2400024HM	Revolution Ace	01008406821461591124090021CBDAG2400024HM	CBDNG2400012HM	Revolution Maxima	01008406821461801124100021CBDNG2400012HM
CBDAG2400025HM	Revolution Ace	01008406821461591124100021CBDAG2400025HM	CBDNG2400013HM	Revolution Maxima	01008406821461801124110021CBDNG2400013HM
CBDAG2400026HM	Revolution Ace	01008406821461591124100021CBDAG2400026HM	CBDNG2400014HM	Revolution Maxima	01008406821461801124120021CBDNG2400014HM
CBDAG2400027HM	Revolution Ace	01008406821461591124100021CBDAG2400027HM	CBDXG2400058HM	Optima CT 680 Expert	01008406821469371124090021CBDXG2400058HM



识别信息	型号	UDI#	识别信息	型号	UDI#
CBFHG2400018HM	Revolution CT ES	0100195278385215(11)240600(21)CBFHG2400018HM	CBDLG2400012HM	Revolution Advance	(01)00195278385215(11)240200(21)CBDLG2400012HM
CBFHG2400035HM	Revolution CT ES	0100195278385215(11)240200(21)CBFHG2400035HM	CBDLG2400013HM	Revolution Advance	(01)00195278385215(11)240200(21)CBDLG2400013HM
CBFHG2400036HM	Revolution CT ES	0100195278385215(11)240200(21)CBFHG2400036HM	CBDLG2400014HM	Revolution Advance	(01)00195278385215(11)240300(21)CBDLG2400014HM
CBFHG2400037HM	Revolution CT ES	0100195278385215(11)240200(21)CBFHG2400037HM	CBDLG2400015HM	Revolution Advance	(01)00195278385215(11)240300(21)CBDLG2400015HM
CBFHG2400038HM	Revolution CT ES	0100195278385215(11)240200(21)CBFHG2400038HM	CBDLG2400016HM	Revolution Advance	(01)00195278385215(11)240300(21)CBDLG2400016HM
CBFHG2400039HM	Revolution CT ES	0100195278385215(11)240200(21)CBFHG2400039HM	CBDLG2400017HM	Revolution Advance	(01)00195278385215(11)240300(21)CBDLG2400017HM
CBFHG2500001HM	Revolution CT ES	0100195278385215(11)250100(21)CBFHG2500001HM	CBDLG2400018HM	Revolution Advance	(01)00195278385215(11)240400(21)CBDLG2400018HM
CBFHG2500002HM	Revolution CT ES	(01)00195278385215(11)250100(21)CBFHG2500002HM	CBDLG2400019HM	Revolution Advance	(01)00195278385215(11)240400(21)CBDLG2400019HM
CBDLG2400001HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400001HM	CBDLG2400020HM	Revolution Advance	(01)00195278385215(11)240400(21)CBDLG2400020HM
CBDLG2400002HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400002HM	CBDLG2400021HM	Revolution Advance	(01)00195278385215(11)240400(21)CBDLG2400021HM
CBDLG2400003HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400003HM	CBDLG2400022HM	Revolution Advance	(01)00195278385215(11)240500(21)CBDLG2400022HM
CBDLG2400004HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400004HM	CBDLG2400023HM	Revolution Advance	(01)00195278385215(11)240500(21)CBDLG2400023HM
CBDLG2400005HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400005HM	CBDLG2400024HM	Revolution Advance	(01)00195278385215(11)240500(21)CBDLG2400024HM
CBDLG2400006HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400006HM	CBDLG2400025HM	Revolution Advance	(01)00195278385215(11)240500(21)CBDLG2400025HM
CBDLG2400007HM	Revolution Advance	(01)00195278385215(11)240100(21)CBDLG2400007HM	CBDLG2400026HM	Revolution Advance	(01)00195278385215(11)240600(21)CBDLG2400026HM
CBDLG2400009HM	Revolution Advance	(01)00195278385215(11)240200(21)CBDLG2400009HM	CBDLG2400027HM	Revolution Advance	(01)00195278385215(11)240600(21)CBDLG2400027HM
CBDLG2400010HM	Revolution Advance	(01)00195278385215(11)240200(21)CBDLG2400010HM	CBDLG2400028HM	Revolution Advance	(01)00195278385215(11)240600(21)CBDLG2400028HM
CBDLG2400011HM	Revolution Advance	(01)00195278385215(11)240200(21)CBDLG2400011HM	CBDLG2400029HM	Revolution Advance	(01)00195278385215(11)240700(21)CBDLG2400029HM
CBDLG2400030HM	Revolution Advance	(01)00195278385215(11)240800(21)CBDLG2400030HM	CBDLG2400031HM	Revolution Advance	(01)00195278385215(11)240800(21)CBDLG2400031HM

识别信息	型号	UDI#	识别信息	型号	UDI#
CBDLG2400032HM	Revolution Advance	(01)00195278385215(11)240800(21)CBDLG2400032HM	CBDLG2400041HM	Revolution Advance	(01)00195278385215(11)241000(21)CBDLG2400041HM
CBDLG2400033HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400033HM	CBDLG2400042HM	Revolution Advance	(01)00195278385215(11)241000(21)CBDLG2400042HM
CBDLG2400034HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400034HM	CBDLG2400043HM	Revolution Advance	(01)00195278385215(11)241000(21)CBDLG2400043HM
CBDLG2400035HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400035HM	CBDLG2400044HM	Revolution Advance	(01)00195278385215(11)241100(21)CBDLG2400044HM
CBDLG2400036HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400036HM	CBDLG2400045HM	Revolution Advance	(01)00195278385215(11)241100(21)CBDLG2400045HM
CBDLG2400037HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400037HM	CBDLG2400046HM	Revolution Advance	(01)00195278385215(11)241100(21)CBDLG2400046HM
CBDLG2400038HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400038HM	CBDLG2400047HM	Revolution Advance	(01)00195278385215(11)241100(21)CBDLG2400047HM
CBDLG2400039HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400039HM	CBDLG2400048HM	Revolution Advance	(01)00195278385215(11)241200(21)CBDLG2400048HM
CBDLG2400040HM	Revolution Advance	(01)00195278385215(11)240900(21)CBDLG2400040HM	CBDLG2400049HM	Revolution Advance	(01)00195278385215(11)241200(21)CBDLG2400049HM

