

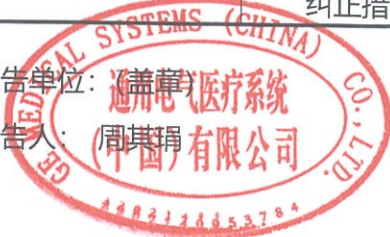
医疗器械召回事件报告表

(公司内部召回编号: FMI 34145)

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	麻醉系统	注册证或备案凭证 编码	国械注准 20173083173
生产企业名称	通用电气医疗系统 (中国) 有限公司		
代理人名称	/		
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 经办人: 周其琚 联系方式: 13816382269		
产品的适用范围	麻醉系统设计用于为多种类型的患者(新生儿、儿童和成人)提供常规吸入式麻醉和呼吸支持。本麻醉系统适合在患者环境中使用, 如医院、手术中心或诊所。本系统仅可由能胜任全身麻醉的合格医师操作。		
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	241 台	涉及产品 型号、规格	型号: Carestation 620、 Carestation 650、Carestation 620 SE; 规格: Carestation 620 A2、 Carestation 650 A2、 Carestation 620 SE A2
识别信息	见 附表 1	涉及产品在中 国的销售数量	241 台
召回原因简述	我司近期发现部分 Carestation 600 V1 麻醉系统不符合 GB9706.255 - 2022 标准。此问题与产品安全或性能无关。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. 发送客户信告知客户关于此问题。 2. 将为客户免费修正受影响的所有产品, 将产品 Carestation 600 从 V1 升级到 V2 (包括硬件、软件和标识), 以满足 GB9706.255 - 2022 标准要求。其中在医院处的设备将会在客户现场进行现场纠正措施, 在经销商处的设备将会返回我司进行纠正措施。		

报告单位:  通用电气医疗系统

报告人: 周其琚

负责人: 李延

报告日期: 2026 年 9 月 7 日



附表 1 识别信息

附表 1-1 在医院处的设备 (140 台)

识别信息	UDI#	识别信息	UDI#
SM624510006WB	(01)00840682124546(21)SM624510006WB(11)241218	SM623250007WB	(01)00840682124546(21)SM623250007WB(11)230620
SM624510007WB	(01)00840682124546(21)SM624510007WB(11)241218	SM624510003WB	(01)00840682124546(21)SM624510003WB(11)241218
SM624510009WB	(01)00840682124546(21)SM624510009WB(11)241218	SM624250019WB	(01)00840682124546(21)SM624250019WB(11)240618
SM624520006WB	(01)00840682124546(21)SM624520006WB(11)241223	SM624250021WB	(01)00840682124546(21)SM624250021WB(11)240618
SM624370030WB	(01)00840682124546(21)SM624370030WB(11)240914	SM624250023WB	(01)00840682124546(21)SM624250023WB(11)240618
SM624240006WB	(01)00840682124546(21)SM624240006WB(11)240613	SM624250029WB	(01)00840682124546(21)SM624250029WB(11)240618
SM624240007WB	(01)00840682124546(21)SM624240007WB(11)240613	SM624120043WB	(01)00840682124546(21)SM624120043WB(11)240322
SM624340004WB	(01)00840682124546(21)SM624340004WB(11)240820	SM624250030WB	(01)00840682124546(21)SM624250030WB(11)240618
SM624340008WB	(01)00840682124546(21)SM624340008WB(11)240820	SM622470013WB	(01)00840682124546(21)SM622470013WB(11)221122
SM624340009WB	(01)00840682124546(21)SM624340009WB(11)240820	SM622370017WB	(01)00840682124546(21)SM622370017WB(11)220917
SM724510219WB	(01)00840682124560(21)SM724510219WB(11)241219	SM622380010WB	(01)00840682124546(21)SM622380010WB(11)220920
SM724510221WB	(01)00840682124560(21)SM724510221WB(11)241219	SM622380011WB	(01)00840682124546(21)SM622380011WB(11)220920
SM723110003WB	(01)00840682124560(21)SM723110003WB(11)230316	SM624250103WB	(01)00840682124546(21)SM624250103WB(11)240622
SM622230050WB	(01)00840682124546(21)SM622230050WB(11)220611	SM622380055WB	(01)00840682124546(21)SM622380055WB(11)220921
SM622230051WB	(01)00840682124546(21)SM622230051WB(11)220611	SM624510030WB	(01)00840682124546(21)SM624510030WB(11)241221
SM624500003WB	(01)00840682124546(21)SM624500003WB(11)241210	SM624510031WB	(01)00840682124546(21)SM624510031WB(11)241221
SM624110008WB	(01)00840682124546(21)SM624110008WB(11)240313	SM724120016WB	(01)00840682124560(21)SM724120016WB(11)240320
SM623500007WB	(01)00840682124546(21)SM623500007WB(11)231212	SM724120017WB	(01)00840682124560(21)SM724120017WB(11)240320
SM724510218WB	(01)00840682124560(21)SM724510218WB(11)241219	SM724120030WB	(01)00840682124560(21)SM724120030WB(11)240320
SM622090008WB	(01)00840682124546(21)SM622090008WB(11)220228	SM724120032WB	(01)00840682124560(21)SM724120032WB(11)240320
SM724120033WB	(01)00840682124560(21)SM724120033WB(11)240320	SM624260027WB	(01)00840682124546(21)SM624260027WB(11)240625
SM624110016WB	(01)00840682124546(21)SM624110016WB(11)240314	SM624260028WB	(01)00840682124546(21)SM624260028WB(11)240625
SM624250105WB	(01)00840682124546(21)SM624250105WB(11)240622	SM624260024WB	(01)00840682124546(21)SM624260024WB(11)240625
SM624520007WB	(01)00840682124546(21)SM624520007WB(11)241225	SM624260025WB	(01)00840682124546(21)SM624260025WB(11)240625
SM624520008WB	(01)00840682124546(21)SM624520008WB(11)241225	SM624330001WB	(01)00840682124546(21)SM624330001WB(11)240812
SM624520009WB	(01)00840682124546(21)SM624520009WB(11)241225	SM624330004WB	(01)00840682124546(21)SM624330004WB(11)240812
SM623370101WB	(01)00840682124546(21)SM623370101WB(11)230912	SM624330005WB	(01)00840682124546(21)SM624330005WB(11)240812
SM623370102WB	(01)00840682124546(21)SM623370102WB(11)230912	SM624330006WB	(01)00840682124546(21)SM624330006WB(11)240812
SM623370103WB	(01)00840682124546(21)SM623370103WB(11)230912	SM624520025WB	(01)00840682124546(21)SM624520025WB(11)241227
SM622260002WB	(01)00840682124546(21)SM622260002WB(11)220628	SM624520026WB	(01)00840682124546(21)SM624520026WB(11)241227
SM624260012WB	(01)00840682124546(21)SM624260012WB(11)240624	SM624250100WB	(01)00840682124546(21)SM624250100WB(11)240622
SM724380135WB	(01)00840682124560(21)SM724380135WB(11)240920	SM624370031WB	(01)00840682124546(21)SM624370031WB(11)240914
SM624370032WB	(01)00840682124546(21)SM624370032WB(11)240914	SM624510013WB	(01)00840682124546(21)SM624510013WB(11)241219
SM624370035WB	(01)00840682124546(21)SM624370035WB(11)240914	SM624520010WB	(01)00840682124546(21)SM624520010WB(11)241225
SM624370037WB	(01)00840682124546(21)SM624370037WB(11)240914	SM624520032WB	(01)00840682124546(21)SM624520032WB(11)241227
SM624370039WB	(01)00840682124546(21)SM624370039WB(11)240914	SM624520033WB	(01)00840682124546(21)SM624520033WB(11)241227
SM624370040WB	(01)00840682124546(21)SM624370040WB(11)240914	SM624520034WB	(01)00840682124546(21)SM624520034WB(11)241227

识别信息	UDI#	识别信息	UDI#
SM624370041WB	(01)00840682124546(21)SM624370041WB(11)240914	SM624260016WB	(01)00840682124546(21)SM624260016WB(11)240625
SM624120042WB	(01)00840682124546(21)SM624120041WB(11)240322	SM624110035WB	(01)00840682124546(21)SM624110035WB(11)240315
SM724510251WB	(01)00840682124560(21)SM724510251WB(11)241220	SM624110036WB	(01)00840682124546(21)SM624110036WB(11)240315
SM724510252WB	(01)00840682124560(21)SM724510252WB(11)241220	SM624110039WB	(01)00840682124546(21)SM624110039WB(11)240315
SM724510205WB	(01)00840682124560(21)SM724510205WB(11)241218	SM723380064WB	(01)00840682124560(21)SM723380064WB(11)230918
SM624510011WB	(01)00840682124546(21)SM624510011WB(11)241219	SM624370026WB	(01)00840682124546(21)SM624370026WB(11)240913
SM624510012WB	(01)00840682124546(21)SM624510012WB(11)241219	SM624370027WB	(01)00840682124546(21)SM624370027WB(11)240913
SM624510027WB	(01)00840682124546(21)SM624510027WB(11)241221	SM724510255WB	(01)00840682124560(21)SM724510255WB(11)241220
SM624520030WB	(01)00840682124546(21)SM624520030WB(11)241227	SM724510256WB	(01)00840682124560(21)SM724510256WB(11)241221
SM624520031WB	(01)00840682124546(21)SM624520031WB(11)241227	SM724510257WB	(01)00840682124560(21)SM724510257WB(11)241221
SM724380134WB	(01)00840682124560(21)SM724380134WB(11)240920	SM724510258WB	(01)00840682124560(21)SM724510258WB(11)241221
SM622120008WB	(01)00840682124546(21)SM622120008WB(11)220322	SM724510267WB	(01)00840682124560(21)SM724510267WB(11)241221
SM624250101WB	(01)00840682124546(21)SM624250101WB(11)240622	SM724510269WB	(01)00840682124560(21)SM724510269WB(11)241221
SM624110015WB	(01)00840682124546(21)SM624110015WB(11)240314	SM724510235WB	(01)00840682124560(21)SM724510235WB(11)241220
SM622230044WB	(01)00840682124546(21)SM622230044WB(11)220611	SM724510236WB	(01)00840682124560(21)SM724510236WB(11)241220
SM622230046WB	(01)00840682124546(21)SM622230046WB(11)220611	SM724510237WB	(01)00840682124560(21)SM724510237WB(11)241220
SM724510253WB	(01)00840682124560(21)SM724510253WB(11)241220	SM723310001WB	(01)00840682124560(21)SM723310001WB(11)230731
SM724510254WB	(01)00840682124560(21)SM724510254WB(11)241220	SM624370033WB	(01)00840682124546(21)SM624370033WB(11)240914
SM624260029WB	(01)00840682124546(21)SM624260029WB(11)240625	SM624370034WB	(01)00840682124546(21)SM624370034WB(11)240914
SM624370036WB	(01)00840682124546(21)SM624370036WB(11)240914	SM624120041WB	(01)00840682124546(21)SM624120041WB(11)240322
SM624370038WB	(01)00840682124546(21)SM624370038WB(11)240914	SM724250029WB	(01)00840682124560(21)SM724250029WB(11)240619
SM624370042WB	(01)00840682124546(21)SM624370042WB(11)240914	SM724510203WB	(01)00840682124560(21)SM724510203WB(11)241218
SM624250020WB	(01)00840682124546(21)SM624250020WB(11)240618	SM624370022WB	(01)00840682124546(21)SM624370022WB(11)240913
SM724510246WB	(01)00840682124560(21)SM724510246WB(11)241220	SM624370023WB	(01)00840682124546(21)SM624370023WB(11)240913
SM724510247WB	(01)00840682124560(21)SM724510247WB(11)241220	SM624370024WB	(01)00840682124546(21)SM624370024WB(11)240913
SM624490015WB	(01)00840682124546(21)SM624490015WB(11)241204	SM624370025WB	(01)00840682124546(21)SM624370025WB(11)240913
SM624490016WB	(01)00840682124546(21)SM624490016WB(11)241204	SM624250081WB	(01)00840682124546(21)SM624250081WB(11)240621
SM724510259WB	(01)00840682124560(21)SM724510259WB(11)241221	SM624250082WB	(01)00840682124546(21)SM624250082WB(11)240621
SM724510260WB	(01)00840682124560(21)SM724510260WB(11)241221	SM624250083WB	(01)00840682124546(21)SM624250083WB(11)240621
SM624330002WB	(01)00840682124546(21)SM624330002WB(11)240812	SM624250084WB	(01)00840682124546(21)SM624250084WB(11)240621
SM624330003WB	(01)00840682124546(21)SM624330003WB(11)240812	SM623130034WB	(01)00840682124546(21)SM623130034WB(11)230327
SM623130036WB	(01)00840682124546(21)SM623130036WB(11)230327	SM622380046WB	(01)00840682124546(21)SM622380046WB(11)220919
SM623130038WB	(01)00840682124546(21)SM623130038WB(11)230327	SM622380048WB	(01)00840682124546(21)SM622380048WB(11)220919

附表 1-2 在经销商处的设备 (101 台)

识别信息	UDI#	识别信息	UDI#
SM724380117WB	(01)00840682124560(21)SM724380117WB(11)240919	SM624510028WB	(01)00840682124546(21)SM624510028WB(11)241221
SM624250001WB	(01)00840682124546(21)SM624250001WB(11)240617	SM624510032WB	(01)00840682124546(21)SM624510032WB(11)241221
SM624380010WB	(01)00840682124546(21)SM624380010WB(11)240919	SM724250015WB	(01)00840682124560(21)SM724250015WB(11)240617
SM624380011WB	(01)00840682124546(21)SM624380011WB(11)240919	SM724250016WB	(01)00840682124560(21)SM724250016WB(11)240617



识别信息	UDI#	识别信息	UDI#
SM724250017WB	(01)00840682124560(21)SM724250017WB(11)240617	SM624050005WB	(01)00840682124546(21)SM624050005WB(11)240130
SM724250018WB	(01)00840682124560(21)SM724250018WB(11)240617	SM624050007WB	(01)00840682124546(21)SM624050007WB(11)240130
SM624490001WB	(01)00840682124546(21)SM624490001WB(11)241202	SM624110017WB	(01)00840682124546(21)SM624110017WB(11)240314
SM624490002WB	(01)00840682124546(21)SM624490002WB(11)241202	SM624110018WB	(01)00840682124546(21)SM624110018WB(11)240314
SM624490003WB	(01)00840682124546(21)SM624490003WB(11)241202	SM624110021WB	(01)00840682124546(21)SM624110021WB(11)240314
SM624490004WB	(01)00840682124546(21)SM624490004WB(11)241202	SM624110022WB	(01)00840682124546(21)SM624110022WB(11)240314
SM624490005WB	(01)00840682124546(21)SM624490005WB(11)241202	SM624110023WB	(01)00840682124546(21)SM624110023WB(11)240314
SM624490006WB	(01)00840682124546(21)SM624490006WB(11)241202	SM724380132WB	(01)00840682124560(21)SM724380132WB(11)240919
SM624490008WB	(01)00840682124546(21)SM624490008WB(11)241204	SM724510261WB	(01)00840682124560(21)SM724510261WB(11)241221
SM724380127WB	(01)00840682124560(21)SM724380127WB(11)240919	SM724510262WB	(01)00840682124560(21)SM724510262WB(11)241221
SM624250036WB	(01)00840682124546(21)SM624250036WB(11)240618	SM724510263WB	(01)00840682124560(21)SM724510263WB(11)241221
SM624250037WB	(01)00840682124546(21)SM624250037WB(11)240618	SM724510264WB	(01)00840682124560(21)SM724510264WB(11)241221
SM624250038WB	(01)00840682124546(21)SM624250038WB(11)240618	SM724510265WB	(01)00840682124560(21)SM724510265WB(11)241221
SM624250039WB	(01)00840682124546(21)SM624250039WB(11)240618	SM624520037WB	(01)00840682124546(21)SM624520037WB(11)241228
SM624250040WB	(01)00840682124546(21)SM624250040WB(11)240618	SM624520038WB	(01)00840682124546(21)SM624520038WB(11)241228
SM623470006WC	(01)00195278569677(21)SM623470006WC(11)231121	SM624520039WB	(01)00840682124546(21)SM624520039WB(11)241228
SM623470007WC	(01)00195278569677(21)SM623470007WC(11)231121	SM624520040WB	(01)00840682124546(21)SM624520040WB(11)241228
SM623470008WC	(01)00195278569677(21)SM623470008WC(11)231121	SM624520041WB	(01)00840682124546(21)SM624520041WB(11)241228
SM623470009WC	(01)00195278569677(21)SM623470009WC(11)231121	SM624520042WB	(01)00840682124546(21)SM624520042WB(11)241228
SM623470010WC	(01)00195278569677(21)SM623470010WC(11)231121	SM624520043WB	(01)00840682124546(21)SM624520043WB(11)241228
SM623470011WC	(01)00195278569677(21)SM623470011WC(11)231121	SM624520044WB	(01)00840682124546(21)SM624520044WB(11)241228
SM623470012WC	(01)00195278569677(21)SM623470012WC(11)231121	SM624520045WB	(01)00840682124546(21)SM624520045WB(11)241228
SM724510250WB	(01)00840682124560(21)SM724510250WB(11)241220	SM624520046WB	(01)00840682124546(21)SM624520046WB(11)241228
SM623240002WB	(01)00840682124546(21)SM623240002WB(11)230613	SM724520280WB	(01)00840682124560(21)SM724520280WB(11)241224
SM623240004WB	(01)00840682124546(21)SM623240004WB(11)230613	SM724520281WB	(01)00840682124560(21)SM724520281WB(11)241224
SM623240005WB	(01)00840682124546(21)SM623240005WB(11)230613	SM724520282WB	(01)00840682124560(21)SM724520282WB(11)241224
SM623500008WB	(01)00840682124546(21)SM623500008WB(11)231212	SM724520283WB	(01)00840682124560(21)SM724520283WB(11)241224
SM623500009WB	(01)00840682124546(21)SM623500009WB(11)231212	SM724520284WB	(01)00840682124560(21)SM724520284WB(11)241224
SM623500010WB	(01)00840682124546(21)SM623500010WB(11)231212	SM724520285WB	(01)00840682124560(21)SM724520285WB(11)241224
SM623500011WB	(01)00840682124546(21)SM623500011WB(11)231212	SM724520286WB	(01)00840682124560(21)SM724520286WB(11)241224
SM623500012WB	(01)00840682124546(21)SM623500012WB(11)231212	SM724520287WB	(01)00840682124560(21)SM724520287WB(11)241224
SM623430179WB	(01)00840682124546(21)SM623430179WB(11)231023	SM724520288WB	(01)00840682124560(21)SM724520288WB(11)241224
SM624050001WB	(01)00840682124546(21)SM624050001WB(11)240130	SM724520289WB	(01)00840682124560(21)SM724520289WB(11)241224
SM724520294WB	(01)00840682124560(21)SM724520294WB(11)241226	SM724520307WB	(01)00840682124560(21)SM724520307WB(11)241228
SM724520295WB	(01)00840682124560(21)SM724520295WB(11)241226	SM724520308WB	(01)00840682124560(21)SM724520308WB(11)241228
SM724520296WB	(01)00840682124560(21)SM724520296WB(11)241226	SM724520309WB	(01)00840682124560(21)SM724520309WB(11)241228
SM724520297WB	(01)00840682124560(21)SM724520297WB(11)241226	SM724520310WB	(01)00840682124560(21)SM724520310WB(11)241228
SM724520298WB	(01)00840682124560(21)SM724520298WB(11)241226	SM724520311WB	(01)00840682124560(21)SM724520311WB(11)241228
SM724520299WB	(01)00840682124560(21)SM724520299WB(11)241226	SM624380002WB	(01)00840682124546(21)SM624380002WB(11)240918
SM724520300WB	(01)00840682124560(21)SM724520300WB(11)241226	SM624380003WB	(01)00840682124546(21)SM624380003WB(11)240918
SM724520301WB	(01)00840682124560(21)SM724520301WB(11)241226	SM624380004WB	(01)00840682124546(21)SM624380004WB(11)240918
SM724520302WB	(01)00840682124560(21)SM724520302WB(11)241228	SM624380005WB	(01)00840682124546(21)SM624380005WB(11)240918



识别信息	UDI#	识别信息	UDI#
SM724520303WB	(01)00840682124560(21)SM724520303WB(11)241228	SM624380006WB	(01)00840682124546(21)SM624380006WB(11)240918
SM724520304WB	(01)00840682124560(21)SM724520304WB(11)241228	SM624390038WB	(01)00840682124546(21)SM624390038WB(11)240924
SM724520305WB	(01)00840682124560(21)SM724520305WB(11)241228	SM624390040WB	(01)00840682124546(21)SM624390040WB(11)240924
SM724520306WB	(01)00840682124560(21)SM724520306WB(11)241228	SM624490012WB	(01)00840682124546(21)SM624490012WB(11)241204
SM624110027WB	(01)00840682124546(21)SM624110027WB(11)240314		

