



# 医疗器械召回事件报告表

(公司内部召回编号: FMI 34104)

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	麻醉系统	注册证或备案 凭证编码	国械注进 20183540068
生产企业名称	Datex-Ohmeda, Inc.		
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: 韦艺 010-57388736 经办人: 彭一苇 010-57388736		
产品的适用范围	Carestation 620/650/650c 麻醉系统预期用于为多种类型的患者(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, 例如医院、手术中心或诊所。此系统预期由能够胜任全身麻醉药的合格临床医师操作		
涉及地区和国家	美国、加拿大、中国 等国家或地区	召回级别	一级
涉及产品生产(或进口中国)批次、数量	408 台	涉及产品 型号、规格	型号: Carestation 620 规格: Carestation 620 A1 Carestation 650 Carestation 650 A1 Carestation 650c Carestation 650c A1
识别信息 (如批号)	见附表 1 识别信息	涉及产品在中国的销售数量	408 台
召回原因简述	<p>本报告为对 GE 医疗中国于 2019 年 12 月 23 日上报的主动召回报告的更新(公司召回编号为 FMI 34104 (沪食药监械主召 2019-307))。主要更新内容为: 召回级别变更为一级召回, 与美国 FDA 分级保持一致。</p> <p>GE 医疗近期发现部分批次产品内的电缆连接可能松动。这可能导致无法使用机械通气功能。</p> <p>GE 医疗中国未收到与该问题相关的国内市场反馈、国内投诉和不良事件相关信息。维护高标准的安全和质量是我们的首要任务, GE 医疗决定主动召回受影响产品。</p>		
纠正行动简述(包括召回要求和处理方式等)	<ol style="list-style-type: none"> <li>1. GE 医疗已通知所有受影响的客户;</li> <li>2. GE 医疗派工程师至现场对受影响的产品进行检查, 如果存在问题, 将帮助更正产品;</li> <li>3. 本次纠正行动不涉及受影响产品的停用及退回。</li> </ol>		

报告单位: (盖章)

报告人: 彭一苇



负责人: 韦艺

首次报告日期: 2019 年 12 月 23 日

本次报告日期: 2020 年 2 月 21 日



附表 1 识别信息

序号	识别号	序号	识别号	序号	识别号	序号	识别号
1	SM618340074MA	103	SM618480039MA	205	SM619070057MA	307	SM718340034MA
2	SM618340075MA	104	SM618480040MA	206	SM619070058MA	308	SM718340035MA
3	SM618340076MA	105	SM618480041MA	207	SM619080025MA	309	SM718340036MA
4	SM618340077MA	106	SM618480042MA	208	SM619080026MA	310	SM718340037MA
5	SM618340083MA	107	SM618480043MA	209	SM619080027MA	311	SM718340038MA
6	SM618360024MA	108	SM618480044MA	210	SM619080028MA	312	SM718340039MA
7	SM618360025MA	109	SM618480045MA	211	SM619080029MA	313	SM718340040MA
8	SM618360026MA	110	SM618480046MA	212	SM619080030MA	314	SM718340041MA
9	SM618370007MA	111	SM618480047MA	213	SM619080031MA	315	SM718340042MA
10	SM618370008MA	112	SM618480048MA	214	SM619080032MA	316	SM718370007MA
11	SM618370009MA	113	SM618480049MA	215	SM619080033MA	317	SM718370008MA
12	SM618370025MA	114	SM618480050MA	216	SM619080034MA	318	SM718370009MA
13	SM618370026MA	115	SM618480051MA	217	SM619080035MA	319	SM718370010MA
14	SM618370027MA	116	SM618480052MA	218	SM619080036MA	320	SM718370016MA
15	SM618370028MA	117	SM618480053MA	219	SM619080037MA	321	SM718370017MA
16	SM618370029MA	118	SM618480054MA	220	SM619080038MA	322	SM718370018MA
17	SM618370030MA	119	SM618480055MA	221	SM619080039MA	323	SM718370019MA
18	SM618370031MA	120	SM618480056MA	222	SM619080040MA	324	SM718370020MA
19	SM618370032MA	121	SM618480057MA	223	SM619090004MA	325	SM718370021MA
20	SM618370033MA	122	SM618480062MA	224	SM619090005MA	326	SM718370022MA
21	SM618370034MA	123	SM618490005MA	225	SM619090006MA	327	SM718370023MA
22	SM618370035MA	124	SM618490006MA	226	SM619090027MA	328	SM718370024MA
23	SM618370036MA	125	SM618490007MA	227	SM619090028MA	329	SM718380014MA
24	SM618370037MA	126	SM618490008MA	228	SM619090029MA	330	SM718380015MA
25	SM618370038MA	127	SM618490009MA	229	SM619090030MA	331	SM718380016MA
26	SM618370039MA	128	SM618490028MA	230	SM619090031MA	332	SM718380017MA
27	SM618370040MA	129	SM618500011MA	231	SM619090032MA	333	SM718380018MA
28	SM618370042MA	130	SM618510001MA	232	SM619090033MA	334	SM718380019MA
29	SM618370043MA	131	SM618510002MA	233	SM619090034MA	335	SM718380020MA
30	SM618370044MA	132	SM619010105MA	234	SM619090035MA	336	SM718380021MA
31	SM618370045MA	133	SM619010106MA	235	SM619090036MA	337	SM718380022MA
32	SM618370046MA	134	SM619010107MA	236	SM619090037MA	338	SM718380023MA
33	SM618370047MA	135	SM619010108MA	237	SM619090038MA	339	SM718400001MA
34	SM618370048MA	136	SM619020013MA	238	SM619100020MA	340	SM718450025MA
35	SM618370049MA	137	SM619030029MA	239	SM619130004MA	341	SM718450060MA
36	SM618370050MA	138	SM619060001MA	240	SM619150010MA	342	SM718450061MA
37	SM618370066MA	139	SM619060002MA	241	SM619150039MA	343	SM718450065MA
38	SM618370067MA	140	SM619060003MA	242	SM619160012MA	344	SM718450066MA
39	SM618380031MA	141	SM619060004MA	243	SM619180001MA	345	SM718460028MA
40	SM618380044MA	142	SM619060005MA	244	SM619180002MA	346	SM718480032MA
41	SM618390003MA	143	SM619060006MA	245	SM619180003MA	347	SM718480033MA
42	SM618390004MA	144	SM619060007MA	246	SM619180004MA	348	SM718480034MA
43	SM618390005MA	145	SM619060008MA	247	SM619180014MA	349	SM718480035MA
44	SM618390006MA	146	SM619060009MA	248	SM619180015MA	350	SM718480036MA



45	SM618410044MA	147	SM619060010MA	249	SM619180016MA	351	SM718480047MA
46	SM618420036MA	148	SM619060011MA	250	SM619190023MA	352	SM718480048MA
47	SM618440022MA	149	SM619060012MA	251	SM619190024MA	353	SM718480049MA
48	SM618440023MA	150	SM619060013MA	252	SM619190026MA	354	SM718480050MA
49	SM618450014MA	151	SM619060014MA	253	SM619190028MA	355	SM718480051MA
50	SM618450015MA	152	SM619060015MA	254	SM619190029MA	356	SM718480052MA
51	SM618450016MA	153	SM619060016MA	255	SM619190034MA	357	SM718480053MA
52	SM618450017MA	154	SM619060017MA	256	SM619190035MA	358	SM718480054MA
53	SM618450023MA	155	SM619060018MA	257	SM619190039MA	359	SM718520019MA
54	SM618450024MA	156	SM619060019MA	258	SM619200024MA	360	SM719060006MA
55	SM618450025MA	157	SM619060020MA	259	SM619200025MA	361	SM719060007MA
56	SM618450026MA	158	SM619060021MA	260	SM619200026MA	362	SM719060008MA
57	SM618450027MA	159	SM619060023MA	261	SM619200027MA	363	SM719060009MA
58	SM618450028MA	160	SM619060024MA	262	SM619200028MA	364	SM719060010MA
59	SM618450029MA	161	SM619060025MA	263	SM619200029MA	365	SM719060011MA
60	SM618450030MA	162	SM619060026MA	264	SM619200030MA	366	SM719060012MA
61	SM618450036MA	163	SM619060027MA	265	SM619200031MA	367	SM719060013MA
62	SM618450037MA	164	SM619060028MA	266	SM619200032MA	368	SM719060014MA
63	SM618450038MA	165	SM619060030MA	267	SM619200033MA	369	SM719060015MA
64	SM618450039MA	166	SM619060031MA	268	SM619200034MA	370	SM719100038MA
65	SM618450040MA	167	SM619060032MA	269	SM619200035MA	371	SM719120006MA
66	SM618450043MA	168	SM619060033MA	270	SM619200036MA	372	SM719120007MA
67	SM618450044MA	169	SM619060034MA	271	SM619200037MA	373	SM719120008MA
68	SM618460004MA	170	SM619060035MA	272	SM619200046MA	374	SM719120009MA
69	SM618460005MA	171	SM619060036MA	273	SM619200047MA	375	SM719120010MA
70	SM618460006MA	172	SM619060037MA	274	SM619200048MA	376	SM719160010MA
71	SM618460007MA	173	SM619060038MA	275	SM619200049MA	377	SM719160011MA
72	SM618460011MA	174	SM619060039MA	276	SM619200050MA	378	SM719170022MA
73	SM618460012MA	175	SM619060040MA	277	SM619200051MA	379	SM719170023MA
74	SM618460013MA	176	SM619060041MA	278	SM619210006MA	380	SM719170024MA
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78	SM618460052MA	180	SM619060065MA	282	SM619210010MA	384	SM719200028MA
79	SM618470010MA	181	SM619060066MA	283	SM619210011MA	385	SM719200029MA
80	SM618480002MA	182	SM619060067MA	284	SM619210012MA	386	SM719210019MA
81	SM618480003MA	183	SM619070005MA	285	SM619210013MA	387	SM719210020MA
82	SM618480004MA	184	SM619070006MA	286	SM619220026MA	388	SM719210021MA
83	SM618480006MA	185	SM619070007MA	287	SM619220027MA	389	SM719210022MA
84	SM618480007MA	186	SM619070008MA	288	SM619220028MA	390	SM719220010MA
85	SM618480008MA	187	SM619070009MA	289	SM619220029MA	391	SM719230036MA
86	SM618480009MA	188	SM619070032MA	290	SM619220030MA	392	SM719230037MA
87	SM618480010MA	189	SM619070041MA	291	SM619220031MA	393	SM719240016MA
88	SM618480011MA	190	SM619070042MA	292	SM619220032MA	394	SM719240017MA
89	SM618480012MA	191	SM619070043MA	293	SM619220033MA	395	SM719270023MA
90	SM618480013MA	192	SM619070044MA	294	SM619220034MA	396	SM719270024MA
91	SM618480014MA	193	SM619070045MA	295	SM619220035MA	397	SM719270025MA
92	SM618480015MA	194	SM619070046MA	296	SM619230003MA	398	SM719270026MA



93	SM618480016MA	195	SM619070047MA	297	SM619230004MA	399	SM719270027MA
94	SM618480017MA	196	SM619070048MA	298	SM619230005MA	400	SM719270028MA
95	SM618480018MA	197	SM619070049MA	299	SM619230018MA	401	SM719270029MA
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97	SM618480020MA	199	SM619070051MA	301	SM619250016MA	403	SM819190001MA
98	SM618480021MA	200	SM619070052MA	302	SM619250017MA	404	SM819190002MA
99	SM618480022MA	201	SM619070053MA	303	SM619250020MA	405	SM819190003MA
100	SM618480023MA	202	SM619070054MA	304	SM619250035MA	406	SM819190004MA
101	SM618480026MA	203	SM619070055MA	305	SM718340025MA	407	SM819190005MA
102	SM618480027MA	204	SM619070056MA	306	SM718340033MA	408	SM819190006MA

