



医疗器械召回事件报告表

(公司内部召回编号: FMI 32073)

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	婴儿保暖台	注册证或备案凭证编码	国食药监械(进)字 2013 第 3541372 号; 国械注进 20163545180
生产企业名称	Ohmeda Medical 和 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	该产品可以通过一种可控的方式为无法通过自身生理机能保持体温调节的婴儿提供红外线辐射热源, 可用于帮助新生儿顺利转移至外部环境或提供一个可控的开放微环境。		
涉及地区和国家	中国、印度、马来西亚等国家和地区	召回级别	二级
涉及产品生产(或进口中国)批次、数量	537 台	涉及产品型号、规格	Lullaby
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	537 台
召回原因简述	<p>本报告为对 GE 医疗于 2020 年 1 月 21 日上报的主动召回报告的更新(公司召回编号为 FMI 32073 (沪食药监械主召 2020-025))。主要更新内容为: 更新产品进口中国数量和在中国销售数量。</p> <p>GE 医疗近期发现, 在不使用温度探头的情况下以手动模式使用该设备时, 加热器可以继续以用户设置的功率运行, 而不会发出报警, 也不会降低输出功率。</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"> 1. 已发送客户信告知客户此问题; 2. GE 医疗派工程师至现场对受影响的产品进行免费修正; 3. 本次纠正行动不涉及受影响产品的停用及退回。 		

报告单位: (盖章)

报告人: 彭一苇



负责人: 韦艺

报告日期: 2020.5.19



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	SF811370872PA	136	SF815484126PA	271	SF816325627PA	406	SF818070098PA
2	SF813312338PA	137	SF815484127PA	272	SF816325628PA	407	SF818070099PA
3	SF813322344PA	138	SF815484136PA	273	SF816325629PA	408	SF818070113PA
4	SF813322345PA	139	SF815484137PA	274	SF816365678PA	409	SF818070114PA
5	SF813322347PA	140	SF815484139PA	275	SF816365689PA	410	SF818070139PA
6	SF813332348PA	141	SF815484140PA	276	SF816395712PA	411	SF818070140PA
7	SF813332359PA	142	SF815484141PA	277	SF816395713PA	412	SF818070141PA
8	SF813332363PA	143	SF815534258PA	278	SF816405725PA	413	SF818070142PA
9	SF813332364PA	144	SF815534259PA	279	SF816405728PA	414	SF818070143PA
10	SF813332365PA	145	SF816064598PA	280	SF816465764PA	415	SF818080002PA
11	SF813332366PA	146	SF816084738PA	281	SF816465767PA	416	SF818080005PA
12	SF813372413PA	147	SF816084739PA	282	SF816465776PA	417	SF818080007PA
13	SF813382421PA	148	SF816084742PA	283	SF816465777PA	418	SF818080008PA
14	SF813382422PA	149	SF816084744PA	284	SF816465784PA	419	SF818080010PA
15	SF813382423PA	150	SF816094745PA	285	SF816465785PA	420	SF818080011PA
16	SF813482545PA	151	SF816094746PA	286	SF816465786PA	421	SF818181008PA
17	SF813482546PA	152	SF816094747PA	287	SF816465787PA	422	SF818181009PA
18	SF813482548PA	153	SF816094749PA	288	SF816465789PA	423	SF818181010PA
19	SF813482549PA	154	SF816094750PA	289	SF816465794PA	424	SF818181011PA
20	SF813482551PA	155	SF816094751PA	290	SF816465795PA	425	SF818181012PA
21	SF813482552PA	156	SF816094752PA	291	SF816465796PA	426	SF818181013PA
22	SF813482553PA	157	SF816094753PA	292	SF816465797PA	427	SF818181014PA
23	SF813492569PA	158	SF816094754PA	293	SF816465798PA	428	SF818181016PA
24	SF813492570PA	159	SF816094756PA	294	SF816465799PA	429	SF818181017PA
25	SF813492572PA	160	SF816094757PA	295	SF816465800PA	430	SF818181018PA
26	SF813492573PA	161	SF816094758PA	296	SF816465801PA	431	SF818181019PA
27	SF813492575PA	162	SF816094759PA	297	SF816465813PA	432	SF818181020PA
28	SF813492576PA	163	SF816094760PA	298	SF816465814PA	433	SF818181022PA
29	SF813492578PA	164	SF816094761PA	299	SF816465815PA	434	SF818181023PA
30	SF814193029PA	165	SF816094763PA	300	SF816475816PA	435	SF818181024PA
31	SF814193031PA	166	SF816094765PA	301	SF816475817PA	436	SF818281019PA
32	SF814193032PA	167	SF816094766PA	302	SF816475818PA	437	SF818291005PA
33	SF814193033PA	168	SF816094767PA	303	SF816475820PA	438	SF818291006PA
34	SF814193034PA	169	SF816094768PA	304	SF816475821PA	439	SF818291010PA
35	SF814193036PA	170	SF816094769PA	305	SF816475823PA	440	SF818291011PA
36	SF814193037PA	171	SF816094770PA	306	SF816475826PA	441	SF818311007PA
37	SF814203060PA	172	SF816094771PA	307	SF816475827PA	442	SF818311008PA
38	SF814203061PA	173	SF816094772PA	308	SF816495901PA	443	SF818341017PA
39	SF814203062PA	174	SF816094774PA	309	SF816495902PA	444	SF818341020PA
40	SF814203063PA	175	SF816094775PA	310	SF816495904PA	445	SF818341025PA
41	SF814203064PA	176	SF816094776PA	311	SF816495905PA	446	SF818341027PA
42	SF814203065PA	177	SF816094777PA	312	SF816495906PA	447	SF818341028PA
43	SF814203074PA	178	SF816094779PA	313	SF816495907PA	448	SF818351005PA
44	SF814203075PA	179	SF816094780PA	314	SF816495908PA	449	SF818351006PA
45	SF814203076PA	180	SF816094781PA	315	SF816495909PA	450	SF818351007PA



46	SF814203077PA	181	SF816094782PA	316	SF816495910PA	451	SF818351008PA
47	SF814213081PA	182	SF816094783PA	317	SF816495911PA	452	SF818351010PA
48	SF814213082PA	183	SF816094784PA	318	SF817136175PA	453	SF818351011PA
49	SF814213083PA	184	SF816094785PA	319	SF817136176PA	454	SF818351012PA
50	SF814213115PA	185	SF816094787PA	320	SF817136177PA	455	SF818351013PA
51	SF814223130PA	186	SF816094789PA	321	SF817136178PA	456	SF818351027PA
52	SF814293157PA	187	SF816094790PA	322	SF817136179PA	457	SF818351028PA
53	SF814293158PA	188	SF816135102PA	323	SF817136180PA	458	SF818361021PA
54	SF814293159PA	189	SF816135103PA	324	SF817146181PA	459	SF818361022PA
55	SF814293160PA	190	SF816135104PA	325	SF817146182PA	460	SF818361023PA
56	SF814293161PA	191	SF816135105PA	326	SF817146183PA	461	SF819041005PA
57	SF814293162PA	192	SF816135106PA	327	SF817146184PA	462	SF819041006PA
58	SF814293163PA	193	SF816135107PA	328	SF817146185PA	463	SF819041007PA
59	SF814293165PA	194	SF816135108PA	329	SF817146186PA	464	SF819041008PA
60	SF814503349PA	195	SF816135110PA	330	SF817146187PA	465	SF819041009PA
61	SF814503350PA	196	SF816135125PA	331	SF817146188PA	466	SF819041022PA
62	SF814503351PA	197	SF816135126PA	332	SF817146189PA	467	SF819041023PA
63	SF814503352PA	198	SF816135127PA	333	SF817146190PA	468	SF819041028PA
64	SF815043424PA	199	SF816135128PA	334	SF817146191PA	469	SF819041029PA
65	SF815043425PA	200	SF816135129PA	335	SF817146192PA	470	SF819041030PA
66	SF815043426PA	201	SF816135130PA	336	SF817146193PA	471	SF819061008PA
67	SF815043427PA	202	SF816135131PA	337	SF817146194PA	472	SF819071014PA
68	SF815043428PA	203	SF816135132PA	338	SF817170002PA	473	SF819071015PA
69	SF815043429PA	204	SF816135133PA	339	SF817170003PA	474	SF819071016PA
70	SF815043430PA	205	SF816135134PA	340	SF817170005PA	475	SF819071017PA
71	SF815053431PA	206	SF816135135PA	341	SF817170018PA	476	SF819071018PA
72	SF815053432PA	207	SF816135137PA	342	SF817170019PA	477	SF819191015PA
73	SF815053433PA	208	SF816135138PA	343	SF817170020PA	478	SF819201018PA
74	SF815053434PA	209	SF816135139PA	344	SF817170061PA	479	SF819201024PA
75	SF815053435PA	210	SF816135140PA	345	SF817170063PA	480	SF819211006PA
76	SF815053436PA	211	SF816135141PA	346	SF817170064PA	481	SF819211009PA
77	SF815053437PA	212	SF816135143PA	347	SF817170065PA	482	SF819211021PA
78	SF815053438PA	213	SF816135144PA	348	SF817170066PA	483	SF819221017PA
79	SF815093518PA	214	SF816135145PA	349	SF817170068PA	484	SF819231012PA
80	SF815093519PA	215	SF816135146PA	350	SF817180001PA	485	SF819241005PA
81	SF815103520PA	216	SF816155312PA	351	SF817180002PA	486	SF819241006PA
82	SF815103521PA	217	SF816155315PA	352	SF817180003PA	487	SF819241007PA
83	SF815113525PA	218	SF816155316PA	353	SF817180004PA	488	SF819241008PA
84	SF815113526PA	219	SF816155318PA	354	SF817180005PA	489	SF819241009PA
85	SF815113527PA	220	SF816155319PA	355	SF817180012PA	490	SF819241010PA
86	SF815113528PA	221	SF816155320PA	356	SF817180013PA	491	SF819241011PA
87	SF815113529PA	222	SF816155321PA	357	SF817180014PA	492	SF819241013PA
88	SF815113530PA	223	SF816155322PA	358	SF817180015PA	493	SF819241014PA
89	SF815153599PA	224	SF816155324PA	359	SF817180016PA	494	SF819241015PA
90	SF815153600PA	225	SF816155325PA	360	SF817180017PA	495	SF819241017PA
91	SF815153601PA	226	SF816175345PA	361	SF817180018PA	496	SF819241018PA
92	SF815153603PA	227	SF816175346PA	362	SF817180019PA	497	SF819261009PA
93	SF815153604PA	228	SF816175347PA	363	SF817290002PA	498	SF819261012PA

94	SF815163606PA	229	SF816175348PA	364	SF817290003PA	499	SF819261018PA
95	SF815163607PA	230	SF816175350PA	365	SF817290004PA	500	SF819261031PA
96	SF815163615PA	231	SF816175352PA	366	SF817290015PA	501	SF819271006PA
97	SF815163616PA	232	SF816175355PA	367	SF817290016PA	502	SF819361011PA
98	SF815163617PA	233	SF816175360PA	368	SF817290017PA	503	SF819361012PA
99	SF815163624PA	234	SF816175361PA	369	SF817290018PA	504	SF819361014PA
100	SF815173628PA	235	SF816175362PA	370	SF817290019PA	505	SF819361015PA
101	SF815173629PA	236	SF816175363PA	371	SF817290035PA	506	SF819361019PA
102	SF815173630PA	237	SF816175364PA	372	SF817290036PA	507	SF819371018PA
103	SF815173631PA	238	SF816175365PA	373	SF817290061PA	508	SF819371019PA
104	SF815173632PA	239	SF816175366PA	374	SF817290063PA	509	SF819371047PA
105	SF815173633PA	240	SF816175367PA	375	SF817290064PA	510	SF819371049PA
106	SF815183636PA	241	SF816185368PA	376	SF817290066PA	511	SF819371051PA
107	SF815183637PA	242	SF816185369PA	377	SF817300017PA	512	SF819371055PA
108	SF815183638PA	243	SF816185370PA	378	SF817300018PA	513	SF819371057PA
109	SF815183639PA	244	SF816185371PA	379	SF817300024PA	514	SF819371058PA
110	SF815183640PA	245	SF816185377PA	380	SF817300025PA	515	SF819371079PA
111	SF815353895PA	246	SF816185378PA	381	SF817340010PA	516	SF819371081PA
112	SF815353896PA	247	SF816185380PA	382	SF817350061PA	517	SF819371082PA
113	SF815353897PA	248	SF816185382PA	383	SF817350099PA	518	SF819371103PA
114	SF815353898PA	249	SF816185384PA	384	SF817350106PA	519	SF819381058PA
115	SF815434017PA	250	SF816185386PA	385	SF817350122PA	520	SF819361016PA
116	SF815434019PA	251	SF816275526PA	386	SF817510042PA	521	SF819371017PA
117	SF815434020PA	252	SF816275527PA	387	SF818030042PA	522	SF819371056PA
118	SF815434021PA	253	SF816275528PA	388	SF818030044PA	523	SF819371060PA
119	SF815444022PA	254	SF816285529PA	389	SF818040028PA	524	SF819371098PA
120	SF815444040PA	255	SF816285534PA	390	SF818040030PA	525	SF819371100PA
121	SF815444041PA	256	SF816285535PA	391	SF818040042PA	526	SF819371101PA
122	SF815444042PA	257	SF816285538PA	392	SF818040043PA	527	SF819371102PA
123	SF815444043PA	258	SF816285540PA	393	SF818040044PA	528	SF819371112PA
124	SF815444044PA	259	SF816285541PA	394	SF818040045PA	529	SF819371113PA
125	SF815444046PA	260	SF816295543PA	395	SF818040056PA	530	SF819371114PA
126	SF815454047PA	261	SF816295544PA	396	SF818060092PA	531	SF819381008PA
127	SF815454048PA	262	SF816295546PA	397	SF818060120PA	532	SF819381021PA
128	SF815454049PA	263	SF816295551PA	398	SF818070054PA	533	SF819381023PA
129	SF815454050PA	264	SF816295552PA	399	SF818070055PA	534	SF819381024PA
130	SF815454051PA	265	SF816295553PA	400	SF818070056PA	535	SF819381025PA
131	SF815454052PA	266	SF816295554PA	401	SF818070064PA	536	SF819381026PA
132	SF815454053PA	267	SF816325620PA	402	SF818070065PA	537	SF819381028PA
133	SF815484123PA	268	SF816325621PA	403	SF818070066PA		
134	SF815484124PA	269	SF816325624PA	404	SF818070096PA		
135	SF815484125PA	270	SF816325626PA	405	SF818070097PA		

