



医疗器械召回事件报告表

(公司内部召回编号: FMI 32094)

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	请见附表 1. 产品信息	注册证或备案凭证编码	请见附表 1. 产品信息
生产企业名称	德恩欧美达公司 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: 李延 010-57388736 经办人: 彭一苇 010-57388736		
产品的适用范围	请见附表 1. 产品信息		
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	1611 件	涉及产品型号、规格	请见附表 1. 产品信息
识别信息(如批号)	见 附表 2. 识别信息	涉及产品在中国的销售数量	1611 件
召回原因简述	GE 医疗近期发现 2018 年 9 月以后发往中国市场的部分上述产品的中文标签上生产日期信息可能印刷不正确。该问题均与产品安全性无关, 为符合法规要求, GE 医疗发起本次主动召回, 以修正标签上的错误信息。		
纠正行动简述(包括召回要求和处理方式等)	1. GE 医疗将通知客户此问题; 2. GE 医疗将为客户免费更正产品中文标签上的错误生产日期信息。 注: 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:

负责人:

报告日期:

李延
2024年8月23日



附表 1 产品信息

产品名称	产品型号	注册证号	产品适用范围
多功能培养箱	Giraffe Omnibed Carestation CS1	国械注进 20153544163 国械注进 20153084163	本产品是婴儿培养箱和婴儿保暖台的组合。根据客户的需要，此设备可作为培养箱或保暖台运行，并可以从一种模式转换为另一种模式。此设备不能同时以两种模式运行。培养箱和保温台以受控的方式为不能依靠自身生理能力进行热调节的新生儿供暖。培养箱提供封闭的温度控制环境，保温台在开放的环境中提供红外供暖。它们也可在短时间内用于帮助新生儿从子宫到外部环境的过渡。
婴儿培养箱	Giraffe Incubator Carestation CS1	国械注进 20183540070 国械注进 20183080070	本产品以受控方式为不能依靠自身生理能力进行体温调节的新生儿提供热量。培养箱通过给婴儿提供封闭的温度控制环境实现此功能。此设备可以集成一个伺服控制供气系统（可选配件），可按操作者设定的值（21-65%）在婴儿培养箱内部提供稳定的氧浓度。
婴儿辐射保暖台	Giraffe	国械注进 20153540683 国械注进 20153080683	婴儿辐射保暖台用于为婴儿和儿科病人提供控制的辐射热源。它可用于帮助新生儿过渡到外部环境，或为婴儿创造一个受控制的开放环境。可选的集成式 SpO2 监测功能可用于对脉搏血氧饱和度（SpO2）和脉率（由 SpO2 传感器测量）进行持续的无创监测。可选的集成式复苏系统可用于为婴儿肺复苏提供必需的基本设备。肺复苏包括保持气道通畅、提供氧气或空气/氧气的混合气体，及/或对婴儿进行手持通气。
	Panda	国械注进 20153540985 国械注进 20153080985	婴儿辐射保暖台用于为婴儿和儿科病人提供控制的辐射热源。它可用于帮助新生儿过渡到外部环境，或为婴儿创造一个受控制的开放环境。可选的集成式 SpO2 监测功能可用于对脉搏血氧饱和度（SpO2）和脉率（由 SpO2 传感器测量）进行持续的无创监测。可选的集成式复苏系统可用于为婴儿肺复苏提供必需的基本设备。肺复苏包括保持气道通畅、提供氧气或空气/氧气的混合气体，及/或对婴儿进行手持通气。

附表 2 识别信息

TAAZ70013	TABY71503	TABX70026	TABB70105	TAAZ70827	TAAA70894	PBWZ70260	PBWC72174	GBWY70665
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TABZ72262	TABY71407	TABD70073	TABB70072	TAAZ70715	TAAA70758	PBWY72923	PBWC70919	GBWY70580
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TABZ70450	TABX70145	TABB71693	TABA70008	TAAC70298	PBWZ70495	PBWX72022	PBWA70498	GBWA70672
TABZ70449	TABX70144	TABB71692	TABA70005	TAAC70297	PBWZ70494	PBWX72021	PBWA70497	GBWA70671
TABZ70448	TABX70143	TABB71687	TAAZ71318	TAAC70284	PBWZ70493	PBWX72019	PBWA70408	GBWA70670
TABZ70447	TABX70142	TABB71683	TAAZ71317	TAAC70283	PBWZ70492	PBWX72018	PBWA70407	GBWA70669
TABZ70446	TABX70141	TABB71682	TAAZ71316	TAAB70565	PBWZ70491	PBWX72017	PBWA70406	GBWA70668
TABZ70444	TABX70140	TABB71627	TAAZ71315	TAAB70558	PBWZ70490	PBWX72016	PBWA70405	GBWA70659
TABZ70443	TABX70139	TABB71602	TAAZ71314	TAAB70555	PBWZ70489	PBWX72015	PBWA70404	GBWA70658
TABZ70442	TABX70138	TABB71597	TAAZ71313	TAAB70553	PBWZ70488	PBWD70004	PBWA70403	GBWA70657
TABZ70441	TABX70137	TABB71593	TAAZ71312	TAAB70551	PBWZ70487	PBWD70003	PBWA70402	GBWA70656
TABZ70208	TABX70136	TABB71579	TAAZ71311	TAAB70350	PBWZ70486	PBWD70002	PBWA70401	GBWA70655
TABZ70167	TABX70094	TABB71568	TAAZ71310	TAAB70349	PBWZ70485	PBWD70001	PBWA70400	GBWA70216
TABZ70166	TABX70093	TABB71565	TAAZ71309	TAAB70339	PBWZ70484	PBWC72686	PBWA70399	GBWA70215
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TABZ70164	TABX70089	TABB71557	TAAZ71307	TAAB70337	PBWZ70482	PBWC72684	PBWA70397	GBWA70213
TABZ70163	TABX70088	TABB71556	TAAZ71306	TAAB70336	PBWZ70481	PBWC72683	PBWA70396	GBWA70212
TABZ70162	TABX70086	TABB71258	TAAZ71305	TAAB70334	PBWZ70480	PBWC72682	PBWA70395	GBWA70211
TABZ70160	TABX70084	TABB71235	TAAZ71304	TAAB70333	PBWZ70479	PBWC72653	PBWA70394	GBWA70209



TABZ70159	TABX70082	TABB71208	TAAZ71282	TAAB70331	PBWZ70478	PBWC72652	PBWA70393	GBWA70208
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TABZ70155	TABX70072	TABB70959	TAAZ71278	TAAA71038	PBWZ70369	PBWC72629	PBWA70389	GBWA70204
TABZ70152	TABX70070	TABB70957	TAAZ71097	TAAA71025	PBWZ70368	PBWC72628	PBWA70186	GBWA70203
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TABZ70149	TABX70065	TABB70903	TAAZ71094	TAAA71002	PBWZ70365	PBWC72625	GBWZ70585	GBWA70190
TABZ70148	TABX70063	TABB70896	TAAZ71083	TAAA70991	PBWZ70359	PBWC72624	GBWZ70584	GBWA70189
TABZ70147	TABX70061	TABB70893	TAAZ71082	TAAA70987	PBWZ70358	PBWC72615	GBWZ70583	GBWA70185
TABZ70146	TABX70059	TABB70892	TAAZ71081	TAAA70985	PBWZ70357	PBWC72614	GBWZ70582	GBWA70154
TABZ70144	TABX70058	TABB70891	TAAZ71080	TAAA70983	PBWZ70356	PBWC72613	GBWZ70581	GBWA70152
TABZ70143	TABX70055	TABB70889	TAAZ71079	TAAA70974	PBWZ70355	PBWC72612	GBWZ70580	GBWA70150
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TABY72021	TABX70053	TABB70415	TAAZ71077	TAAA70949	PBWZ70353	PBWC72610	GBWZ70578	GBWA70133
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TABY72017	TABX70045	TABB70389	TAAZ71074	TAAA70938	PBWZ70350	PBWC72586	GBWZ70575	GBWA70130
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TABY72013	TABX70043	TABB70301	TAAZ71072	TAAA70934	PBWZ70348	PBWC72584	GBWZ70573	GBWA70128
TABY72009	TABX70042	TABB70296	TAAZ71071	TAAA70930	PBWZ70347	PBWC72583	GBWZ70570	GBWA70127
TABY72005	TABX70041	TABB70293	TAAZ71070	TAAA70928	PBWZ70346	PBWC72184	GBWZ70569	GBWA70126
TABY72003	TABX70040	TABB70290	TAAZ71069	TAAA70926	PBWZ70345	PBWC72183	GBWZ70568	GBWA70125
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TABY71998	TABX70034	TABB70279	TAAZ70834	TAAA70924	PBWZ70267	PBWC72181	GBWZ70565	GBWA70118
TABY71996	TABX70033	TABB70277	TAAZ70833	TAAA70920	PBWZ70266	PBWC72180	GBWZ70564	GBWA70116
TABY71995	TABX70032	TABB70268	TAAZ70832	TAAA70916	PBWZ70265	PBWC72179	GBWZ70563	GBWA70115
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TABY71993	TABX70030	TABB70255	TAAZ70830	TAAA70908	PBWZ70263	PBWC72177	GBWY70668	GBWA70112
TABY71992	TABX70029	TABB70249	TAAZ70829	TAAA70901	PBWZ70262	PBWC72176	GBWY70667	GBWA70111
TABY71991	TABX70028	TABB70106	TAAZ70828	TAAA70898	PBWZ70261	PBWC72175	GBWY70666	GBWA70110