

附件 1

## 医疗器械召回事件报告表

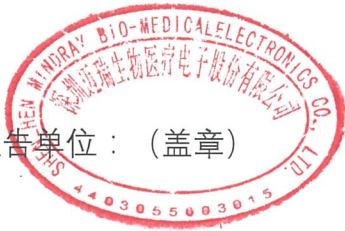
提交：企业所在地省级食品药品监督管理部门

器械注册/备案部门

产品名称	彩色多普勒超声系统	注册证或备案凭证编码	粤械注准 20182230139 粤械注准 20182230242 粤械注准 20182230383 粤械注准 20192061111
生产企业名称	深圳迈瑞生物医疗电子股份有限公司		
代理人名称	/		
召回单位负责人联系方式, 经办人和联系方式	深圳迈瑞生物医疗电子股份有限公司(以下简称“深圳迈瑞”) 联系人: 夏红芳 联系方式: 0755-81885612, mr@mindray.com		
产品的适用范围	用于临床超声诊断检查		
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	DC-70 系列 294 台 DC-90 36 台	涉及产品型号、规格	DC-70 系列 DC-90

<p>识别信息 (如批号)</p>	<p>见附件</p>	<p>涉及产品在 中国的销售数量</p>	<p>330 台</p>
<p>召回原因简述</p>	<p>1、深圳迈瑞在电磁兼容性测试中发现，部分彩色多普勒超声系统，在高频段的特定单频点下，其最大电磁辐射强度可能不符合产品技术要求，根据相关法规要求，深圳迈瑞决定发起主动召回。 2、产品的其它性能和参数均合格，可正常使用。</p>		
<p>纠正行动简述(包括召回 要求和处理方式等)</p>	<p>1、根据 GB 8702-2014 等相关标准，上述产品最大电磁辐射强度远低于电磁环境控制的耐受限值和环境中电磁辐射抗干扰等级的要求。本次召回不涉及产品的更改，用户可继续正常使用该仪器。 2、深圳迈瑞将通知客户关于此召回的内容。</p>		

报告单位：(盖章)



负责人：(签字)

陈刚

报告人：(签字)

陈刚

报告日期：2020.11.23

附件：

受影响产品序列号			
CW8-04000033	CW8-0A000096	CW8-09000083	CJ1-07001625
CW8-04000035	CW8-0A000098	CW8-09000084	CJ1-07001629
CW8-04000041	CW8-0A000099	CW8-09000085	CJ1-07001632
CW8-05000054	CW8-0A000100	CW8-09000086	CJ1-07001633
CW8-05000055	CW8-0A000103	CW8-09000087	CJ1-07001634
CW8-06000062	CW8-0A000104	CW8-09000088	CJ1-07001635
CW8-06000065	CJ1-05001577	CW8-09000089	CJ1-07001638
CW8-07000068	CJ1-05001578	CW8-09000090	CJ1-07001639
CW8-07000069	CJ1-05001579	CW8-09000091	CJ1-07001640
CW8-07000070	CJ1-05001580	CW8-09000092	CJ1-07001641
CW8-07000071	CJ1-06001581	CW8-0A000094	CJ1-07001642
CW8-07000074	CJ1-06001582	CW8-0A000095	CJ1-08001653
CW8-07000075	CJ1-06001583	CJ1-08001654	CJ1-0A001766
CW8-08000076	CJ1-06001584	CJ1-08001655	CJ1-0A001767
CW8-08000077	CJ1-06001585	CJ1-08001656	CJ1-0A001779
CW8-08000078	CJ1-06001586	CJ1-08001657	CJ4-05001113
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CW8-08000082	CJ1-06001596	CJ1-08001673	CJ4-06001120

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