

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	心脏瓣膜成形环 Annuloplasty Ring 瓣膜成形环 Annuloplasty System 心脏瓣膜成形环 Tricuspid Annuloplasty Ring 瓣膜成形环 Annuloplasty ring 心包生物瓣膜 Pericardial Bioprosthesis 心包生物瓣膜 Pericardial Bioprosthesis 心包生物瓣膜 Pericardial Bioprosthesis 干式主动脉瓣膜 EDWARDS INSPIRIS RESILIA Aortic Valve 干式二尖瓣瓣膜 Mitris Resilia Mitral Valve	注册证或 备案凭证 编码	国械注进 20163133017 国械注进 20173136528 国械注进 20173136532 国械注进 20183130206 国械注进 20163133012 国械注进 20163133322 国械注进 20173135078 国械注进 20203130521 国械注进 20243130603
生产企业名称	Edwards Lifesciences LLC 爱德华兹生命科学有限责任公司		
代理人名称	爱德华（上海）医疗用品有限公司		
召回单位负责人和联系方式， 经办人和联系方式	负责人：宋蕾 021-53891848 经办人：王珊珊 021-53891801		
产品的适用范围	国械注进 20163133017：该产品用于各种因瓣环扩张所致的先天性或后天性的二尖瓣关闭不全，除了严重的先天性畸形和瓣膜退行性病变。 国械注进 20173136528：该产品用于二尖瓣和三尖瓣的修复。 国械注进 20173136532：用于纠正病理性瓣环扩张，增加瓣膜结合面积，加固已成形的三尖瓣瓣环缝合线和防止瓣环再次过度扩张。 国械注进 20183130206：该产品适用于三尖瓣关闭不全患者，可纠正瓣环扩大、		

	增加瓣叶接合、加固瓣环缝合线以及防止瓣环过度扩大。 国械注进 20163133012: 该产品用于行天然或人工二尖瓣置换术的患者。 国械注进 20163133322: 7300TFX 型生物瓣膜适用于行天然或人工二尖瓣置换术的患者。3300TFX 型生物瓣膜适用于行天然或人工主动脉瓣置换术的患者。 国械注进 20173135078: 该产品用于主动脉瓣病已严重至需使用人工瓣膜替代其天然瓣膜的患者。它还适用于既往植入的人工主动脉瓣已不能正常工作且需要更换的患者。在后一种情况下, 既往植入的人工瓣膜应通过外科手术切除, 并用人工瓣膜置换。 国械注进 20203130521: 该产品适用于天然或人工主动脉心脏瓣膜的置换。 国械注进 20243130603: 该产品适用于行天然或人工二尖瓣置换术的患者。		
涉及地区和国家	美国、英国、加拿大、澳大利亚等	召回级别	三级召回
涉及产品生产 (或进口 中国) 批次、数量	0、0	涉及产品 型号、规格	见附件
识别信息 (如批号)	见附件	涉及产品 在中国的 销售数量	无
召回原因简述	注册人近期在境外发现少数“患者植入卡”上信息存在出入(如产品型号、序列号等)。该问题不涉及产品质量, 也不影响产品本身的性能, 仅与提供给患者的植入卡信息有关。该问题不会导致患者的安全风险。		
纠正行动简述 (包括召回要求 和处理方式 等)	中国未进口销售受影响批次产品, 除上报药监局外, 无需采取其他措施。		

报告单位: (盖章)

负责人: (签字)

报告人: (签字)

报告日期:

附件-产品规格、型号及识别信息

型号、规格	UDI DI	序列号
11400M25	00690103205534	9432149,9427980,10687728
11400M27	00690103205541	8689071,9457650,9883679,10226421,10496856
11400M29	00690103205558	10399659
11400M31	00690103205565	10360278,10273560,10360178,10497441
11400M33	00690103205572	10453559,10736074,11033034,8101050,10143487,10782111,11843562,11843394
11500A19	00690103194968	8160574,5899014,8343303,10620007
11500A21	00690103194975	6946662,7522150,9185962,9185964,9913641,6413351,9468770,8045499,9168556,9609385,7049288,7910333,9192114,5881454,6137913,6253260,6663983,7049185,7060719,7060737,7060974,7611631,7825272,7878106,9324935,9418112,9468783,9556501,9775820,9686603,9686752
11500A23	00690103194982	6414313,6542866,6934699,7298990,7937489,8145225,9476353,10182751,11037554,10607443,6195985,10830033,6222873,10710751,6542916,6834817,10033836,11022132,7409332,8055835,8174924,8503349,11118022,8204905,9165136,9696777,10037398,10075363,5426765,6640461,10598306,5867679,7016017,7916720,9343019,9462138,9546180,9546181,10044308,5731207,5809252,5827093,6221976,6222176,6704335,7015816,7467559,7683691,7742299,7916750,9207829,9291680,9330152,9404525,9433056,9469265,9479042,9484533,9696413,9995691,10048151,10062456,10594648,10097259,9279286,10640179,10182579,10532127,10615637,10991384,9485526,11702680
11500A25	00690103194999	7571970,5899260,6438341,7365514,7800763,7814096,8056776,9246252,9355976,9589677,9590223,10397567,10427164,10431304,11276554,11276820,11344566,11255970,6314370,6820847,6890368,9655400,7911494,7411176,10097623,6366870,6787665,6315136,6802029,8523181,8866563,9643762,6025233,6837956,5994152,8056567,9588395,9597206,9767749,10394569,6226277,6244494,6664787,6664903,6890431,6890451,6890480,7128773,7365598,7523282,7542607,7702080,7702243,7800751,7895157,8023426,8896123,9244419,9246041,9522956,9625927,9712357,9833693,7523585,7895181,9269521,9781717,10273715,10532621,10608799,10665713,10940125,10097695,9708159,9650584,10048949,10731143,11177568,11177213
11500A27	00690103195002	6367479,7516239,7516240,7516308,7684188,7880822,9339324,9375079,9555913,10274243,10360594,7128856,6227632,10294505,10393987,6802772,7177443,8045638,6745614,6396138,7351338,11877587,5901419,6136896,6227418,6233686,6569187,6640819,7390648,7468193,7468297,7722766,8938653,9425620,9712062,9785278,7986318,8045849,11162617,9548128

11500A29	00690103195019	7881003,8146265,11078229,9877315,10182091,6202329,6069896,6228061,7218855,9601720,10182144,6196066,6326837,6706916,7250644,7276558,7315139,7351544,8658652,9945427,10368153,11318949,11715136,9601721,6694632,10604552
2800TFX23	00690103194098	6965739
3300TFX19	00690103176124	5334370,3186284,4467348,4601739,4953352,4734849,6247572
3300TFX21	00690103176131	10328144,5709104,5035605,10180683,5600371,4288985,5181869,5660261
3300TFX23	00690103176148	4639900,4759119,7274525,4631063,10200348,4818124,4545523,5841369,9335937
3300TFX25	00690103176155	10056546,10056548,8380798,4009324,10321896,10989676,8469065,10744493,5711518,6785105,10097120,9306368
3300TFX27	00690103176162	6645598,5677798,6018007,6739649,7354581
3300TFX29	00690103176179	5712826
4450M28	00690103020236	7526317
4450M32	00690103020250	10004546
4450M34	00690103020267	8466821
4450M36	00690103020274	8430985
4450M38	00690103020281	10267723
4600G36L	07612989000549	5259374,6518540
4600G38L	07612989000556	10408777,9515637
4900T28	00690103182279	11326355,10224894,9934409,10464615
5200M28	00690103180190	11114583
5200M30	00690103180206	10747915,10937011,4594631,4426482,7716765
5200M32	00690103180213	11179590
5200M34	00690103180220	11527538
5200M36	00690103180237	4868002,4728726,7110483,11916292,10624643
5200M38	00690103180244	5156860,10869903
6200T26	00690103188431	10439520
6200T28	00690103188448	11017198
6200T30	00690103188455	8625771,10770285
6200T32	00690103188462	10656666
6900PTFX25	00690103163582	6151844,5996565,6057978,6089949,6104770,6115475
6900PTFX27	00690103163599	5970061,6017639,5864171,5894386,6085326,6126470,6158908,5975737
7300TFX25	00690103186253	4936637
7300TFX27	00690103186260	5612079,9649144
7300TFX29	00690103186277	3628497,9213290,3604080,9214171,7349981
7300TFX31	00690103186284	6759642
7300TFX33	00690103186291	5465894,10498533,6634369