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	全自动细菌培养系统 全自动核酸提纯及荧光PCR分析系统 全自动微生物鉴定药敏分析仪 全自动细菌培养系统 全自动细菌培养系统	注册证或备案凭证编码	国械注进20162223234 国械注进20143225420 国械注进20172222301 国械注进20182221553 国食药监械(进)字2011第2402840号
生产企业名称	碧迪公司Becton, Dickinson and Company		
召回单位负责人和联系方式，经办人和联系方式	负责人：凌晓云　　联系方式：021-23254526 经办人：刘彦燕　　联系方式：021-23254837		
产品的适用范围	国械注进20143225420：该产品基于全自动核酸提取及实时荧光定量PCR技术，与配套的检测试剂共同使用，在临床上用于对来源于人体样本中的核酸进行定量或定性检测。 国械注进20162223234：该产品通过检测与二氧化碳反应而变化的荧光强度来判断微生物生长的原理，与BD BACTEC配套血培养瓶联合使用，用于临床上快速培养、检测血液和体液标本中需氧菌、厌氧菌、真菌和分枝杆菌。 国械注进20172222301：该产品采用一系列常规的显色和荧光生化测试原理进行微生物鉴定，采用基于培养基的微量稀释测试原理进行药敏试验，与配套的检测试剂共同使用，在临床上用于对来源于人体经培养纯化的具有临床意义的需氧和兼性厌氧的革兰氏阳性细菌，需氧和兼性厌氧的革兰氏阴性细菌、酵母菌及酵母菌样真菌进行鉴定，并对具有临床意义的需氧和兼性厌氧的革兰氏阳性细菌，需氧和兼性厌氧的革兰氏阴性细菌进行药敏试验。 国械注进20182221553：用于对来源于人体的血液和其他体液样本的细菌及真菌的培养检测。 国食药监械(进)字2011第2402840号：该产品在医学临床上用于快速培养、检测血液和体液标本中需氧菌、厌氧菌、真菌和分枝杆菌。		
涉及地区和国家	全球	召回级别	三级
涉及产品生产（或进口中国）批次、数量	3516台	涉及产品型号、规格	国械注进20143225420：BD MAX Clinical 国械注进20162223234：BACTEC FX 国械注进20172222301：BD Phoenix M50 国械注进20182221553：BD BACTEC FX40 国食药监械(进)字2011第2402840号：BD BACTEC 9120

识别信息（如批号）	详见附件	涉及产品在中国的销售数量	3516台
召回原因简述	BD 监测信息技术环境时发现，信息技术 (IT) 环境的有限部分遭到未经授权的访问。BD 终止了未经授权的访问并采取了额外的安全措施。未经授权的行为者访问了 BD 技术支持团队用于某些 BD 产品的产品服务凭证。在这些产品服务凭证更新之前，存在未经授权访问的风险，未经授权访问 BD 仪器/系统可能会使仪器失效、损坏或暴露仪器/系统数据库或修改诊断测试结果。仪器失效可能会延误适当的诊断和治疗。数据损坏或结果篡改（结果可能是假阳性或假阴性）可能会导致诊断错误和治疗不当或缺失。		
纠正行动简述（包括召回要求和处理方式等）	1、向相关客户发出通知函，告知此次召回原因。 2、对于受影响产品采取适当的纠正措施（包括更新软件）。 3、要求客户在使用设备时，采取 IT、安全和安保措施，加强授权人员管理、相关设备设置防火墙，并限制访问权限。		

报告单位：（盖章）　　负 责 人：（签字）

报 告 人：（签字）　　报告日期：

2024.11.21

附表：受影响产品序列号

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UB3812	UB1792	UB4882	UB5573
UB5324	UB0031	UB4717	UB5282
UB5381	UB3709	UB4948	UB5368
UB4504	UB4740	UB4936	UB3055
UB5364	UB3479	UB4939	UB5385
UB3785	UB1793	UB4942	UB3570
UB5397	UB1750	UB4839	UB5270
UB4420	UB1057	UB4744	UB5314
UB5433	UB0097	UB4836	UB3042
UB5434	UB1048	UB4891	UB5323
UB4481	UB3696	UB4777	UB3493
UB5425	UB5102	UB4954	UB5461
UB5502	UB5209	UB4884	UB4231
UB4346	UB5607	UB4808	UB3636
UB4507	UB3655	UB4774	UB3706
UB5371	UB5561	UB4965	UB1934
UB5141	UB5517	UB4957	UB3424
UB5379	UB5602	UB4933	UB4245
UB5244	UB5614	UB4968	UB5313
UB4554	UB5622	UB4984	UB5416
UB4567	UB5616	UB4989	UB5458
UB4620	UB5634	UB4679	UB5260
UB4057	UB3912	UB4769	UB5467
UB4424	UB5630	UB4970	UB4333
UB4614	UB3929	UB5037	UB4354
UB5483	UB5645	UB5031	UB5435
UB5303	UB5643	UB4982	UB4339
UB5374	UB5649	UB5018	UB4872
UB4115	UB5651	UB5014	UB4342
UB5375	UB5653	UB4985	UB5272
UB1983	UB5655	UB5044	UB3768
UB4084	UB4064		