

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	血气分析仪	注册证或 备案凭证 编码	国械注进 20172221953
生产企业名称	雷度米特医疗设备有限公司 Radiometer Medical ApS		
代理人名称	雷度米特医疗设备（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：吴静霞 联系方式：60158488 经办人：赵海燕 联系方式：021-60158547		
产品的适用范围	该产品基于电化学原理和光学原理，与配套的电极和定标液共同使用，在临床上用于对来源于人体的全血、呼出气体、其他体液样本中的被分析物进行定量检测，包括pH、二氧化碳分压（pCO ₂ ）、氧分压（pO ₂ ）、钙离子（Ca ²⁺ ）、钾离子（K ⁺ ）、钠离子（Na ⁺ ）、氯离子（Cl ⁻ ）、葡萄糖（Glu）、乳酸（Lac）、胆红素（tBil）、总血红蛋白浓度（ctHb）、动脉氧饱和度（sO ₂ ）、动脉氧合血红蛋白分数（FO ₂ Hb）、动脉碳氧血红蛋白分数（FCO ₂ Hb）、动脉高铁血红蛋白分数（F _{Met} Hb）、胎儿血红蛋白分数（FHbF）、还原血红蛋白分数（FH _{Hb} ）项目。		
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	600台	涉及产品型号、规格	ABL800 FLEX
识别信息（如批号）	序列号详见附件	涉及产品在中国的销售数量	600台
召回原因简述	雷度米特已意识到血气分析仪ABL800 FLEX的一个潜在问题。根据内部和外部用户关于定标时有pH灵敏度以及漂移错误和质控时pH值超出范围的报告，进行了一项内部技术研究。 研究得出结论，有微乎其微的可能性，血液样本的pH值偏差超限。		
纠正行动简述（包括召回要求和处理方式等）	雷度米特将： 联系每个受影响的客户，向客户提交召回忠告函，或者以拜访客户方式来递交召回忠告函，并且解释问题所在； 收到客户确认已实施召回客户忠告函中所述行动，并收集客户反馈表，报告持有人丹麦雷度米特医疗设备有限公司。 用户行动： 从即刻起，雷度米特要求运行日常质控的用户执行“程序1”，要求不运行日常质控的用户执行“程序2”。相关程序，请参阅召回客户忠告函。 填写召回回复表（召回客户忠告函第5页），并在收到后两周内将其提交给雷度米特代表。		



报告单位：（盖章）
报告人：（签字）

赵海燕

负责人：（签字） 吴静霞
报告日期： 2024-06-04

附件

机器序列号	机器序列号	机器序列号	机器序列号	机器序列号	机器序列号
754R0349N007	754R1132N003	754R1451N006	754R1847N004	754R2461N009	754R2703N016
754R0388N011	754R1145N006	754R1452N005	754R1848N001	754R2461N010	754R2703N017
754R0390N009	754R1146N004	754R1452N007	754R1852N001	754R2463N001	754R2706N021
754R0402N012	754R1162N004	754R1453N002	754R1852N004	754R2463N002	754R2706N022
754R0403N002	754R1162N006	754R1453N003	754R1853N002	754R2463N004	754R2706N023
754R0403N003	754R1162N007	754R1453N004	754R1858N002	754R2463N020	754R2706N026
754R0403N004	754R1163N001	754R1454N005	754R1863N003	754R2464N002	754R2709N024
754R0418N004	754R1175N001	754R1454N006	754R1868N005	754R2469N006	754R2709N025
754R0422N006	754R1178N004	754R1455N001	754R1868N008	754R2484N003	754R2709N027
754R0422N010	754R1179N005	754R1455N004	754R1872N004	754R2489N002	754R2709N029
754R0433N012	754R1179N008	754R1462N002	754R1872N005	754R2505N003	754R2723N011
754R0436N007	754R1182N004	754R1466N003	754R1873N001	754R2505N006	754R2724N019
754R0449N010	754R1195N008	754R1469N001	754R1885N001	754R2505N007	754R2724N020
754R0512N001	754R1203N004	754R1485N001	754R1914N007	754R2505N008	754R2733N033
754R0512N002	754R1207N002	754R1522N001	754R1915N004	754R2506N004	754R2734N002
754R0520N008	754R1207N003	754R1533N002	754R1916N006	754R2507N006	754R2736N007
754R0520N011	754R1208N004	754R1537N007	754R1917N003	754R2510N004	754R2736N017
754R0539N006	754R1211N008	754R1539N006	754R1918N002	754R2516N008	754R2736N018
754R0554N005	754R1218N001	754R1547N007	754R1918N003	754R2519N013	754R2737N035
754R0573N003	754R1218N004	754R1548N003	754R1918N004	754R2521N003	754R2737N037
754R0579N004	754R1219N002	754R1549N003	754R1918N005	754R2521N010	754R2738N036
754R0579N005	754R1225N004	754R1551N007	754R1918N006	754R2521N012	754R2738N039
754R0579N006	754R1225N007	754R1560N005	754R1918N007	754R2521N014	754R2738N040
754R0601N010	754R1226N010	754R1563N001	754R1918N008	754R2523N009	754R2739N020
754R0605N001	754R1226N011	754R1563N002	754R1919N003	754R2528N011	754R2739N021
754R0686N008	754R1230N005	754R1564N005	754R1919N007	754R2533N010	754R2741N024
754R0689N004	754R1231N011	754R1566N006	754R1919N008	754R2535N015	754R2742N007
754R0691N001	754R1232N002	754R1567N006	754R1920N001	754R2535N016	754R2749N001
754R0715N009	754R1232N004	754R1568N002	754R1920N002	754R2536N002	754R2749N002
754R0717N004	754R1232N005	754R1568N005	754R1920N004	754R2536N009	754R2749N003
754R0727N001	754R1234N004	754R1576N001	754R1920N008	754R2537N002	754R2749N012
754R0749N003	754R1234N010	754R1576N006	754R1921N001	754R2537N010	754R2749N013
754R0750N001	754R1234N011	754R1579N007	754R1921N002	754R2537N011	754R2755N012
754R0751N001	754R1236N005	754R1581N003	754R1921N006	754R2537N012	754R2755N032
754R0752N005	754R1236N006	754R1581N006	754R1923N004	754R2537N014	754R2755N033
754R0757N001	754R1236N007	754R1612N002	754R1923N005	754R2544N005	754R2755N034
754R0776N006	754R1237N006	754R1612N003	754R1923N007	754R2544N006	754R2759N011
754R0781N006	754R1238N006	754R1641N005	754R1924N008	754R2556N011	754R2764N014
754R0796N002	754R1238N007	754R1643N003	754R1945N005	754R2556N022	754R2771N001
754R0798N002	754R1239N011	754R1643N004	754R1946N005	754R2557N004	754R2776N016
754R0799N001	754R1241N011	754R1643N007	754R1946N006	754R2558N004	754R2776N017
754R0799N003	754R1284N007	754R1662N008	754R1947N005	754R2562N001	754R2781N006
754R0800N007	754R1284N008	754R1663N005	754R1949N006	754R2562N010	754R2781N009
754R0802N008	754R1285N005	754R1664N004	754R1950N001	754R2563N003	754R2783N007
754R0803N007	754R1285N007	754R1665N001	754R1953N005	754R2577N017	754R2783N008
754R0804N004	754R1289N001	754R1665N002	754R1999N007	754R2581N002	754R2786N003
754R0814N007	754R1299N006	754R1666N002	754R2046N006	754R2598N006	754R2786N006
754R0826N002	754R1299N007	754R1666N003	754R2048N006	754R2600N008	754R2787N028
754R0826N005	754R1300N001	754R1666N006	754R2048N008	754R2600N009	754R2787N049
754R0826N007	754R1300N003	754R1666N007	754R2057N006	754R2608N001	754R2788N017
754R0847N006	754R1300N006	754R1667N002	754R2071N004	754R2608N006	754R2788N018
754R0848N001	754R1313N004	754R1667N004	754R2072N001	754R2610N001	754R2788N028
754R0866N004	754R1315N003	754R1667N007	754R2072N002	754R2610N002	754R2790N027
754R0870N007	754R1316N002	754R1667N008	754R2075N002	754R2610N003	754R2790N030
754R0871N002	754R1328N005	754R1677N001	754R2083N003	754R2620N003	754R2790N034
754R0881N005	754R1328N006	754R1677N002	754R2106N004	754R2620N004	754R2791N006
754R0885N001	754R1328N007	754R1679N002	754R2121N004	754R2634N007	754R2791N007



754R0885N002	754R1329N001	754R1679N003	754R2121N005	754R2634N008	754R2792N039
754R0889N002	754R1329N002	754R1683N004	754R2121N006	754R2634N009	754R2792N041
754R0899N004	754R1331N002	754R1685N005	754R2124N002	754R2641N008	754R2793N004
754R0909N006	754R1331N004	754R1686N001	754R2124N003	754R2643N016	754R2793N006
754R0912N003	754R1331N005	754R1686N005	754R2127N007	754R2643N018	754R2793N007
754R0914N006	754R1334N006	754R1687N008	754R2128N002	754R2644N001	754R2793N009
754R0914N007	754R1337N001	754R1690N006	754R2128N004	754R2644N002	754R2795N014
754R0914N008	754R1337N002	754R1690N007	754R2128N005	754R2644N007	754R2795N016
754R0916N002	754R1337N005	754R1690N008	754R2128N006	754R2650N014	754R2795N021
754R0925N001	754R1350N005	754R1690N009	754R2143N004	754R2650N015	754R2795N023
754R0935N001	754R1350N007	754R1694N003	754R2143N005	754R2651N001	754R2795N024
754R0935N006	754R1355N003	754R1694N005	754R2181N003	754R2651N002	754R2798N029
754R0955N008	754R1355N008	754R1696N006	754R2182N007	754R2653N013	754R2801N050
754R0958N005	754R1356N002	754R1696N009	754R2215N006	754R2654N001	754R2802N003
754R0958N006	754R1356N003	754R1700N008	754R2216N001	754R2656N012	754R2802N004
754R0958N009	754R1357N005	754R1701N001	754R2218N003	754R2657N001	754R2802N007
754R0971N001	754R1370N007	754R1701N002	754R2218N004	754R2657N002	754R2802N049
754R0976N007	754R1371N009	754R1701N004	754R2219N005	754R2657N003	754R2803N003
754R0977N006	754R1372N003	754R1708N009	754R2219N006	754R2662N008	754R2803N013
754R0997N002	754R1372N005	754R1724N002	754R2220N004	754R2662N009	754R2803N018
754R0997N006	754R1372N006	754R1724N005	754R2220N005	754R2662N010	754R2803N020
754R0997N009	754R1373N005	754R1724N006	754R2225N004	754R2663N017	754R2806N014
754R1000N009	754R1374N006	754R1728N003	754R2226N001	754R2663N018	754R2809N021
754R1007N004	754R1379N002	754R1728N007	754R2248N006	754R2663N019	754R2811N005
754R1021N008	754R1381N003	754R1729N001	754R2264N004	754R2664N020	754R2811N007
754R1043N002	754R1382N001	754R1729N002	754R2317N002	754R2666N003	754R2811N009
754R1043N004	754R1384N006	754R1729N005	754R2321N005	754R2666N007	754R2812N031
754R1070N002	754R1388N004	754R1749N005	754R2323N008	754R2666N009	754R2814N011
754R1074N008	754R1392N003	754R1766N005	754R2327N003	754R2668N009	754R2814N020
754R1075N001	754R1393N003	754R1766N006	754R2334N003	754R2673N013	754R2814N023
754R1075N002	754R1407N003	754R1773N007	754R2334N004	754R2673N014	754R2815N014
754R1075N006	754R1429N002	754R1780N007	754R2335N003	754R2677N002	754R2815N019
754R1075N008	754R1431N006	754R1786N006	754R2337N006	754R2677N012	754R2816N021
754R1090N004	754R1431N008	754R1786N007	754R2337N007	754R2695N012	754R2816N025
754R1104N006	754R1437N003	754R1786N008	754R2338N001	754R2695N013	754R2818N010
754R1106N003	754R1437N004	754R1787N001	754R2341N001	754R2695N014	754R2818N011
754R1106N005	754R1441N001	754R1808N008	754R2341N002	754R2695N015	754R2818N035
754R1107N002	754R1441N002	754R1809N002	754R2414N008	754R2697N012	754R2821N017
754R1107N003	754R1441N007	754R1810N002	754R2414N010	754R2701N022	754R2821N018
754R1113N006	754R1442N001	754R1813N005	754R2415N006	754R2701N024	754R2821N020
754R1124N005	754R1442N004	754R1813N006	754R2415N010	754R2701N026	754R2821N022
754R1131N005	754R1443N010	754R1814N003	754R2417N002	754R2702N013	754R2823N003
754R1131N007	754R1451N003	754R1814N007	754R2445N005	754R2703N009	754R2827N020

