



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	胰岛素注射泵	注册证或备案凭证编码	国械注进 20173141951
生产企业名称	美敦力泌力美公司 Medtronic MiniMed		
代理人名称	美敦力（上海）管理有限公司		
召回单位负责人和联系方式，经办人和联系方式	负责人：吴 懿 021-20325954 经办人：刘 博 021-20325855		
产品的适用范围	该产品用于以设定的各种速度（包括基础率和大剂量）通过皮下途径持续输注胰岛素，以满足糖尿病患者治疗中的个性化胰岛素需要。胰岛素注射泵接收的血糖值不可作为糖尿病的诊断和筛查的依据，也不可作为治疗药物调整的依据，仅用于让患者了解自己当前的血糖水平。		
涉及地区和国家	全球	召回级别	一级
涉及产品生产（或进口中国）批次、数量	1763 个	涉及产品型号、规格	型号描述：遥控器 型号：MMT-503EU
识别信息（如批号）	详见 附表一	涉及产品在中国的销售数量	1763 个
召回原因简述	美敦力通过调查发现 MMT-503EU 遥控器相关的潜在安全漏洞。当胰岛素注射泵的用户在使用遥控器进行大剂量输注时，用户附近的恶意人员有可能通过用户的遥控器来复制无线射频信号，并在后期回放这些信号，向用户输注非自愿的大剂量胰岛素，或者暂停/恢复胰岛素泵的输注。须注意，利用此漏洞进行攻击需要专业技术技能和专用设备。此外，攻击只能对原射频信号所针对的泵进行，而无法攻击其他泵，因为其他泵尚未使用遥控器的标识编号进行编程。 本次受影响产品为遥控器，胰岛素注射泵性能等各方面均无问		

	<p>题可正常使用。截至 2021 年 10 月为止，我司尚未收到使用漏洞进行攻击的事件，也没有与该问题相关的投诉或网络安全事件。</p>
<p>纠正行动简述（包括召回要求和处理方式等）</p>	<ol style="list-style-type: none"> 1. 在美敦力中国官网及美敦力官方相关微信公众号上发布该召回信息 2. 美敦力将向上述销售涉及的经销商和医院及个人用户发送医疗器械主动召回通知函并回收确认函，要求立即停止经营或使用受影响的产品并通知其断开遥控器，禁用遥控功能，然后将遥控器退回 3. 最终受影响产品退回后将会被统一隔离在我司仓库，根据最终处置决定退回原厂。

报告单位：美敦力（上海）管理有限公司

负责人：吴懿

报告人：刘博

报告日期：2021 年 11 月 19 日



附表一 中国受影响产品清单（型号：MMT-503EU，总计1763个），序列号如下

CMR345790H	CMR345795H	CMR353618H	CMR353620H	CMR353621H	CMR353622H	CMR353627H	CMR353629H	CMR353629H	CMR353629H
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CMR370252H	CMR368964H	CMR370314H	CMR370315H	CMR370316H	CMR371372H	CMR371373H	CMR371375H	CMR370306H	CMR369004H
CMR368955H	CMR368956H	CMR368957H	CMR368954H	CMR368953H	CMR368952H	CMR368951H	CMR369002H	CMR371378H	CMR370308H
CMR371380H	CMR368971H	CMR368972H	CMR368973H	CMR370254H	CMR370255H	CMR370256H	CMR368974H	CMR368994H	CMR371379H
CMR370264H	CMR370289H	CMR370290H	CMR370291H	CMR370292H	CMR370293H	CMR370294H	CMR370296H	CMR366718H	CMR366720H
CMR366721H	CMR366722H	CMR369110H	CMR369109H	CMR369108H	CMR369107H	CMR36907H	CMR369012H	CMR369013H	CMR369016H
CMR369014H	CMR369015H	CMR369113H	CMR369114H	CMR369115H	CMR369116H	CMR369224H	CMR369225H	CMR369223H	CMR369164H
CMR369165H	CMR369222H	CMR369133H	CMR369135H	CMR369134H	CMR369136H	CMR369163H	CMR369162H	CMR369161H	CMR369160H
CMR369159H	CMR369158H	CMR369157H	CMR369156H	CMR369155H	CMR369154H	CMR369153H	CMR369152H	CMR369151H	CMR369150H
CMR369142H	CMR369141H	CMR369137H	CMR369117H	CMR369132H	CMR369124H	CMR369123H	CMR369122H	CMR369121H	CMR369120H
CMR369119H	CMR369118H	CMR369291H	CMR369292H	CMR369295H	CMR369226H	CMR369227H	CMR369228H	CMR369312H	CMR369313H
CMR369315H	CMR369316H	CMR369319H	CMR369278H	CMR369237H	CMR369238H	CMR369239H	CMR369305H	CMR369307H	CMR369308H
CMR369309H	CMR369310H	CMR369246H	CMR369245H	CMR369244H	CMR369284H	CMR369283H	CMR369282H	CMR369299H	CMR369296H
CMR369236H	CMR369230H	CMR369276H	CMR369272H	CMR369271H	CMR369247H	CMR369311H	CMR369243H	CMR369242H	CMR369241H
CMR369240H	CMR369304H	CMR369303H	CMR369302H	CMR369301H	CMR369334H	CMR369333H	CMR369331H	CMR369328H	CMR369325H
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CMR370828H	CMR370829H	CMR370831H	CMR370830H	CMR370832H	CMR370836H	CMR370837H	CMR370838H	CMR370839H	CMR370841H
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CMR375042H	CMR375043H	CMR375044H	CMR375045H	CMR375047H	CMR375048H	CMR375049H	CMR375050H	CMR375051H	CMR375052H
CMR375055H	CMR375056H	CMR375057H	CMR375058H	CMR371917H	CMR371918H	CMR375062H	CMR375061H	CMR375059H	CMR375060H
CMR375039H	CMR375027H	CMR375025H	CMR375024H	CMR375022H	CMR375021H	CMR375020H	CMR375019H	CMR375018H	CMR375017H
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CMR375067H	CMR375069H	CMR375075H	CMR375076H	CMR375085H	CMR375104H	CMR375140H	CMR375141H	CMR375143H	CMR375144H
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CMR377823H	CMR377824H	CMR353568H	/	/	/	/	/	/	/