

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	外周球囊扩张导管 NanoCross Elite 0.014” Over-the-Wire PTA Balloon Dilatation Catheter	注册证或备案 凭证编码	国械注进 20193030436
生产企业名称	Medtronic, Inc.		
代理人名称	德康医疗器械国际贸易（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：胡萍 021-20325859 经办人：王文韬 021-20325375		
产品的适用范围	国械注进 20193030436：该器械适用于扩张髂动脉、股动脉、髂股动脉、腘动脉、腘下动脉和肾动脉中的狭窄以及用于治疗自体或合成动静脉透析瘘的阻塞性病变。该器械还适用于外周血管中的支架后扩张。		
涉及地区和国家	美国;日本;意大利;德国	召回级别	二级召回
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	详见报告表
识别信息 （如批号）	详见报告表	涉及产品在 中国的销售数量	0
召回原因简述	2024 年 9 月的投诉趋势调查发现，针对 5 毫米和 6 毫米球囊尺寸的 NanoCross Elite 放气困难投诉数量有所增加，经调查发现该问题可能与制造相关。		
纠正行动简述（包括召回要求和处理方式等）	不适用，受影响产品未进口至中国，无需采取纠正行动。		

报告单位：慈惠医疗器械国际贸易（上海）有限公司
报 告 人：文 韬



负 责 人：胡 萍

报告日期：2025 年 5 月 29 日

AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050200090	NANOCROSS ELITE 5MM X 200MM X 90CM	00763000758172
AB14W050200090	NANOCROSS ELITE 5MM X 200MM X 90CM	04987742337815
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050080150	NANOCROSS ELITE 5MM X 80MM X 150CM	00763000758103
AB14W060080150	NANOCROSS ELITE 6MM X 80MM X 150CM	00763000758264
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W050020150	NANOCROSS ELITE 5MM X 20MM X 150CM	00763000758042
AB14W060150150	NANOCROSS ELITE 6MM X 150MM X 150CM	00763000758325
AB14W050080150	NANOCROSS ELITE 5MM X 80MM X 150CM	00763000758103
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W050060150	NANOCROSS ELITE 5MM X 60MM X 150CM	00763000758080
AB14W050120150	NANOCROSS ELITE 5MM X 120MM X 150CM	00763000758141
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050120150	NANOCROSS ELITE 5MM X 120MM X 150CM	00763000758141
AB14W060120150	NANOCROSS ELITE 6MM X 120MM X 150CM	00763000758301
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W050080150	NANOCROSS ELITE 5MM X 80MM X 150CM	00763000758103
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W060080150	NANOCROSS ELITE 6MM X 80MM X 150CM	00763000758264
AB14W060060150	NANOCROSS ELITE 6MM X 60MM X 150CM	00763000758240
AB14W060080150	NANOCROSS ELITE 6MM X 80MM X 150CM	00763000758264
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W050060150	NANOCROSS ELITE 5MM X 60MM X 150CM	00763000758080
AB14W060100150	NANOCROSS ELITE 6MM X 100MM X 150CM	00763000758288
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W060060150	NANOCROSS ELITE 6MM X 60MM X 150CM	00763000758240
AB14W060080150	NANOCROSS ELITE 6MM X 80MM X 150CM	00763000758264
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050020090	NANOCROSS ELITE 5MM X 20MM X 90CM	00763000758035
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W060120150	NANOCROSS ELITE 6MM X 120MM X 150CM	00763000758301
AB14W050120150	NANOCROSS ELITE 5MM X 120MM X 150CM	00763000758141
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W060100150	NANOCROSS ELITE 6MM X 100MM X 150CM	00763000758288
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349



AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W050040150	NANOCROSS ELITE 5MM X 20MM X 150CM	00763000758066
AB14W050080150	NANOCROSS ELITE 5MM X 20MM X 150CM	00763000758103
AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W060150150	NANOCROSS ELITE 6MM X 150MM X 150CM	00763000758325
AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W050020150	NANOCROSS ELITE 5MM X 20MM X 150CM	00763000758042
AB14W060150150	NANOCROSS ELITE 6MM X 150MM X 150CM	00763000758325
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W060100150	NANOCROSS ELITE 6MM X 100MM X 150CM	00763000758288
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W060120150	NANOCROSS ELITE 6MM X 120MM X 150CM	00763000758301
AB14W050200090	NANOCROSS ELITE 5MM X 200MM X 90CM	00763000758172
AB14W060060150	NANOCROSS ELITE 6MM X 60MM X 150CM	00763000758240
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W060150150	NANOCROSS ELITE 6MM X 150MM X 150CM	00763000758325
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W060200150	NANOCROSS ELITE 6MM X 200MM X 150CM	00763000758349
AB14W060100150	NANOCROSS ELITE 6MM X 100MM X 150CM	00763000758288
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050060150	NANOCROSS ELITE 5MM X 60MM X 150CM	00763000758080
AB14W050040150	NANOCROSS ELITE 5MM X 40MM X 150CM	00763000758066
AB14W060040150	NANOCROSS ELITE 6MM X 40MM X 150CM	00763000758226
AB14W050150150	NANOCROSS ELITE 5MM X 150MM X 150CM	00763000758165
AB14W050120150	NANOCROSS ELITE 5MM X 120MM X 150CM	00763000758141
AB14W060080150	NANOCROSS ELITE 6MM X 80MM X 150CM	00763000758264
AB14W050080150	NANOCROSS ELITE 5MM X 80MM X 150CM	00763000758103
AB14W050020150	NANOCROSS ELITE 5MM X 20MM X 150CM	00763000758042
AB14W060040090	NANOCROSS ELITE 6MM X 40MM X 90CM	00763000758219
AB14W050080090	NANOCROSS ELITE 5MM X 80MM X 90CM	00763000758097
AB14W050200150	NANOCROSS ELITE 5MM X 200MM X 150CM	00763000758189
AB14W050100150	NANOCROSS ELITE 5MM X 100MM X 150CM	00763000758127