



## MEDICAL DEVICE RECALL LISTING APRIL 2025

No.	Date Received	Reference Number	Recall Type	Product Name	Product Registration Number	Recall Class	Reason for Recall	Recalling Establishment	Establishment Licence
1.	09/04/2025	MDA/Recall/P0383-73149245-2025	Establishment (Voluntary Recall)	ON-X ASCENDING AORTIC PROSTHESIS AND ON-X HEART VALVE INSTRUMENTS	GD8557723-147098	Class III :Low Risk	A02: Manufacturing, Packaging or Shipping Problem	MEDI-LIFE (M) SDN. BHD.	MDA-4741-WDP123
2.	16/04/2025	MDA/Recall/P0385-64232512-2025	Establishment (Voluntary Recall)	CODMAN DISPOSABLE PERFORATOR	GB52719760018	Class I :High Risk	A05: Mechanical Problem	SCHMIDT BIOMEDTECH SDN BHD	MDA-5076-WDP123
3.	16/04/2025	MDA/Recall/P0384-18438503-2025	Establishment (Voluntary Recall)	TUFTEX EMBOLECTOMY CATHETERS	GB2580023-125507	Class II :Moderate Risk	A02: Manufacturing, Packaging or Shipping Problem	ANDAMAN MEDICAL BRIDGE SDN. BHD.	MDA-5221-W123
4.	16/04/2025	MDA/Recall/P0386-42568042-2025	Establishment (Voluntary Recall)	PRUITT OCCLUSION CATHETER	GB2509622-104128				
5.	16/04/2025	MDA/Recall/P0387-59432765-2025	Establishment (Voluntary Recall)	PRUITT IRRIGATION OCCLUSION CATHETER	GB2128122-101561				
6.	18/04/2025	MDA/Recall/P0388-64500684-2025	Establishment (Voluntary Recall)	HINOTORI SURGICAL ROBOT SYSTEM	GC8683624-179851	Class II :Moderate Risk	A04: Material Integrity Problem	SYSMEX (MALAYSIA) SDN. BHD.	MDA-4997-WDP123
7.	25/04/2025	MDA/Recall/P0390-38191321-2025	Establishment (Voluntary Recall)	TORNADO EMBOLIZATION COILS AND MICROCOILS	GD34698117417	Class II :Moderate Risk	A02: Manufacturing, Packaging or Shipping Problem	COOK ASIA (MALAYSIA) SDN BHD	MDA-5123-WDP123