MEDICAL DEVICE RECALL LISTING DECEMBER 2025

No.	Date Received	Reference Number	Recall Type	Product Name	Product Registration Number	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
1.	23/12/2025	MDA/Recall/P0462-53037605-2025	Establishment (Voluntary Recall)	DENGUE COMBO RAPID TEST CASSETTE	IVDC6802724-187762	Class III: Low Risk	A02: Manufacturing, Packaging or Shipping Problem	MEDEXP SDN BHD	MDA-5793-WDP124
2.	05/12/2025	MDA/Recall/P0465-23252092-2025	Establishment (Voluntary Recall)	ABRE VENOUS SELF-EXPANDING STENT SYSTEM	GC4860424-182045	Class II: Moderate Risk	A04: Material Integrity Problem	MEDTRONIC MALAYSIA SDN BHD	MDA-4793-WDP123
3.	19/12/2025	MDA/Recall/P0470-60985031-2025	Establishment (Voluntary Recall)	SURGICAL TISSUE MANAGEMENT SYSTEM	GC57003616918	Class II: Moderate Risk	A05: Mechanical Problem	OLYMPUS (MALAYSIA) SDN. BHD.	MDA-2218-WDP121
4.	25/12/2025	MDA/Recall/P0471-96490080-2025	Establishment (Voluntary Recall)	HOT AXIOS STENT AND DELIVERY SYSTEM	GC44673513317	Class II: Moderate Risk	A01: Patient Device Interaction Problem	BOSTON SCIENTIFIC (MALAYSIA) SDN BHD	MDA-5810-WD124

* The information contained in the Medical Device Authority Recall database is released under Regulation 7(8) and Regulation 8 (5) of Malaysia's Medical Device Regulations 2019.