MEDICAL DEVICE RECALL LISTING AUGUST 2026

No.	Date Received	Reference Number	Recall Type	Product Name	Product Registration Number	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
1.	10/08/2026	MDA/Recall/P0544-21470823-2026	Voluntary Recall	BICOAG HEMOSTASIS PROBE	GC68151232317	Class II	A02: Manufacturing, Packaging or Shipping Problem	OLYMPUS (MALAYSIA) SDN. BHD.	MDA-2218-WDP121
2.	10/08/2026	MDA/Recall/P0546-89366368-2026	Voluntary Recall	COBAS 5800	IVDA4563422-99323	Class III	A02: Manufacturing, Packaging or Shipping Problem	COBAS 5800	IVDA4563422-99323
3.	12/08/2026	MDA/Recall/P0547-15827738-2026	Voluntary Recall	CONFIRM™ ANTI-ALK1 (ALK01) PRIMARY ANTIBODY	IVDC10803623-151207	Class III: Low Risk	A02: Manufacturing, Packaging or Shipping Problem	CONFIRM™ ANTI-ALK1 (ALK01) PRIMARY ANTIBODY	IVDC10803623-151207
4.	26/08/2026	MDA/Recall/P0548-24312385-2026	Voluntary Recall	DA VINCI XI SURGICAL SYSTEM, ENDOSCOPIC INSTRUMENT CONTROL SYSTEM, MODEL IS4000	GC3810021-64842	Class II	A27: Appropriate Term/Code Not Available	DTG MEDICAL SDN BHD	MDA-4091-WDP122

MEDICAL DEVICE RECALL LISTING AUGUST 2026

5.	26/08/2026	MDA/Recall/P0549-25780413-2026	Voluntary Recall	DA VINCI SI SURGICAL SYSTEM, ENDOSCOPIC INSTRUMENT CONTROL SYSTEM, MODEL IS3000	GC74543334017	Class II	A27: Appropriate Term/Code Not Available	DTG MEDICAL SDN BHD	MDA-4091-WDP122

* 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.