



MEDICAL DEVICE RECALL LISTING MAY 2025

No .	Date Received	Reference Number	Recall Type	Product Name	Product Registration Number	Recall Class	Reason for Recall	Recalling Establishment	Establishment Licence
1.	02/05/2025	MDA/Recall/P03 95-44283051-2025	Establishment (Voluntary Recall)	THE BELMONT HYPERTHERMIA PUMP	GC89158618618	Class III: Low Risk	A02: Manufacturing, Packaging or Shipping Problem	TRANSMEDIC HEALTHCARE SDN BHD	MDA-4762-WDP123
2.	05/05/2025	MDA/Recall/P03 96-20208974-2025	Establishment (Voluntary Recall)	CONSTELLATION VISION SYSTEM	GC96073327017	Class II: Moderate Risk	A02: Manufacturing, Packaging or Shipping Problem	ALCON LABORATORIES (M) SDN. BHD.	MDA-5021-W123
3.	19/05/2025	MDA/Recall/P03 98-53257259-2025	Establishment (Voluntary Recall)	ARTHREX LATERAL SHOULDER POSITIONERS	GA3588823-156337	Class III :Low Risk	A02: Manufacturing, Packaging or Shipping Problem	TRANSMEDIC HEALTHCARE SDN BHD	MDA-4762-WDP123
4.	21/05/2025	MDA/Recall/P03 97-38465380-2025	Establishment (Voluntary Recall)	ROBOTIC ARM INTERACTIVE ORTHOPAEDIC SYSTEM (RIO)	GC593731188118	Class III :Low Risk	A04: Material Integrity Problem	STRYKER CORPORATION (MALAYSIA) SDN. BHD.	MDA-5657-WDP124
5.	23/05/2025	MDA/Recall/P04 01-59649142-2025	Establishment (Voluntary Recall)	SUSCEPTIBILITY AND IDENTIFICATION TEST FOR MYCOBACTERIA	IVDC23724200218	Class II :Moderate Risk	A23: Use of Device Problem	BECTON DICKINSON SDN BHD	MDA-5083-W123

6.	23/05/2025	MDA/Recall/P04 02-10337300- 2025	Establishment (Voluntary Recall)	ALINITY I TOTAL PSA	IVDC86110274 518	Class II :Moderate Risk	A09: Output Problem	ABBOTT LABORATORIES (MALAYSIA) SDN. BHD.	MDA-5104- W123
7.	23/05/2025	MDA/Recall/P04 03-473567260- 2025	Establishment (Voluntary Recall)	STA® - NEOPTIMAL	IVDC6519023- 137999	Class III :Low Risk	A27: Appropriate Term/Code Not Available	ALL EIGHTS (M) SDN BHD	MDA-4259- WDP123
8.	26/05/2025	MDA/Recall/P04 04-92745620- 2025	Establishment (Voluntary Recall)	ARTERIAL PERFUSION CANNULA	GD7681622- 82736	Class II :Moderate Risk	A02: Manufacturing, Packaging or Shipping Problem	EDWARDS LIFESCIENCES (MALAYSIA) SDN BHD	MDA-4697- WDP123