MEDICAL DEVICE RECALL LISTING NOVEMBER 2023

Date Received	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
02/11/2023	MDA/Recall/P0212-72826560-2023	Voluntary Recall	EVOLUTION 3E SYSTEM AND ACCESSORIES	GB661621228518	Class III	A02: Manufacturing, Packaging or Shipping Problem	MANDARIN OPTO-MEDIC SDN BHD	MDA-4750-WDP123
09/11/2023	MDA/Recall/P0141-50000072-2023	Voluntary Recall	INJETAK ADJUSTABLE TIP NEEDLES	GB142131040418	Class III	A23: Use of Device Problem	MKS MEDIC SDN BHD	MDA-1358-WDP120
10/11/2023	MDA/Recall/PX0220-74798217-2023	Voluntary Recall	DRUG ELUTING PTCA BALLOON CATHETER	GD78955336517	Class III	A21: Labelling, Instructions for Use or Training Problem	B. BRAUN MEDICAL INDUSTRIES SDN BHD	MDA-4250-W123
21/11/2023	MDA/Recall/P0224-40067213-2023	Voluntary Recall	LIAISON® CHLAMYDIA TRACHOMATIS	IVDC4404721-55981	Class III	A08: Calibration Problem	DIAGNOSTICARE SDN BHD	MDA-4336-WDP123
29/11/2023	MDA/Recall/P0225-45953445-2023	Voluntary Recall	DIASYS SUBSTRATE KIDYNEY PROFILE	IVDB5581820-40159	Class III	A08: Calibration Problem	SYSMEX (MALAYSIA) SDN BHD	MDA-4997-WDP123

* 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.