MEDICAL DEVICE RECALL LISTING JULY & AUGUST 2022

Date of Reporting	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
21 July 2022	MDA/Recall/P0007-33934132-2022	Voluntary Recall	ROADRUNNER UNIGLIDE HYDROPHILIC WIRE GUIDE	GB377741336919	Class I	A02: Manufacturing, Packaging or Shipping Problem	**COOK ASIA (MALAYSIA) SDN BHD**	MDA-1987-WDP121
26 July 2022	MDA/Recall/P0011-43386148-2022	Voluntary Recall	CONNECTORS-MICROCLAVE	GB385541106018	Class III	A02: Manufacturing, Packaging or Shipping Problem	**EMERGING SYSTEMS (M) SDN. BHD.**	MDA-1614-WDP121
26 July 2022	MDA/Recall/P0012-50437904-2022	Voluntary Recall	SURPLUG	GMD64687955619A	Class III	A02: Manufacturing, Packaging or Shipping Problem	**TERUMO MALAYSIA SDN. BHD.**	MDA-0794-WDP120
29 July 2022	MDA/PMSV/R2022-034	Voluntary Recall	ARIES HSV 1&2 ASSAY	IVDC44297287118	Class III	A02: Manufacturing, Packaging or Shipping Problem	**BMS DIAGNOSTIC (M) SDN. BHD.**	MDA-2047-WDP121
01 August 2022	MDA/Recall/P0008-11130643-2022	Voluntary Recall	BREATH-O CORRECT	GB531851277619	Class II	A02: Manufacturing, Packaging or Shipping Problem	**SEED CONTACT LENS (M) SDN. BHD.**	MDA-0673-WDP67319

MEDICAL DEVICE RECALL LISTING JULY & AUGUST 2022

01 August 2022	MDA/Recall/P0022-83389236-2022	Voluntary Recall	ENNOVATE SPINAL SYSTEM IMPLANT	GC57325621618	Class III	A21: Labelling, Instructions for Use or Training Problem	**B. BRAUN MEDICAL INDUSTRIES SDN BHD**	MDA-0078-W7814
01 August 2022	MDA/Recall/P0022-83389237-2022	Voluntary Recall	HOLLOW FIBER DIALYZER	GC97124670918	Class III	A14: Infusion or Flow Problem	**B. BRAUN MEDICAL INDUSTRIES SDN BHD**	MDA-0078-W7814
03 August 2022	MDA/Recall/P0035-56210981-2022	Voluntary Recall	ADSORBA HEMOPERFUSION CARTRIDGE	GC32251831818	Class I	A02: Manufacturing, Packaging or Shipping Problem	**BAXTER HEALTHCARE (MALAYSIA) SDN. BHD.**	MDA-1025-WDP120
24 August 2022	MDA/Recall/P0047-67120902-2022	Voluntary Recall	VENTANA MEDICAL SYSTEMS_HISTOLOGY/CYTOLOGY_ HISTOLOGY/CYTOLOGY REAGENTS	IVDA2775457417	Class III	A21: Labelling, Instructions for Use or Training Problem	**ROCHE DIAGNOSTICS (M) SDN. BHD. B-20-1 LEVEL 20 THE**	MDA-1674-WDP121
25 August 2022	MDA/Recall/P0043-18482428-2022	Voluntary Recall	IMMUCLONE BLOOD GROUPING REAGENTS FOR KELL SYSTEM	IVDD7684924217	Class III	A21: Labelling, Instructions for Use or Training Problem	**BMS DIAGNOSTICS (M) SDN BHD**	MDA-2047-WDP121
27 August 2022	MDA/Recall/P0049-78561612-2022	Voluntary Recall	HEARTWARE VENTRICULAR ASSIST SYSTEM (HVAD)	GD74345985518	Class II	A02: Manufacturing, Packaging or Shipping Problem	**MEDTRONIC MALAYSIA SDN BHD**	MDA-0074-WDP7414

* 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.