MEDICAL DEVICE RECALL LISTING MARCH 2022

Date Received	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
9 March 2022	MDA/PMSV/R2022-013	Voluntary recall	Architect STAT Myoglobin Calibrators	IVDC61829231718	Class III	A08: Calibrator problem	Abbott Laboratories (Malaysia) Sdn. Bhd.	MDA-1685-W121
12 March 2022	MDA/PMSV/R2022-014	Voluntary recall	Alere NT-proBNP for ARCHITECT & Alinity i	IVDC9794819-26769 IVDC7664219-34593	Class III	A27: Appropriate term/ code not available (Regulatory issue)	Abbott Diagnostics Health Sdn. Bhd.	MDA-1894-WD121
15 March 2022	MDA/PMSV/R2022-015	Voluntary recall	Triathlon® Primary/Tritanium Tibial Baseplates	GD42222611618 GC48361787918 GD54307362817	Class III	A21: Labelling, instruction for use or training problems	Stryker Corporation (Malaysia) Sdn. Bhd.	MDA-2123-WDP121
17 March 2022	MDA/PMSV/R2022-016	Voluntary recall	ROTAPROTM Atherectomy System (ROTAWIRE Drive and wireClip Torquer)	GD6612419-26977	Class III	A02: Manufacturing, Packaging or Shipping Problem	Boston Scientific (M) Sdn. Bhd.	MDA-1754-WDP121
18 March 2022	MDA/PMSV/R2022-017	Voluntary recall	GELITA-SPON® , Absorbable Gelatin Sponge Hemostat	GD97157451717	Class III	A18: Contamination / decontamination Problem	IDS MEDICAL SYSTEMS (M) Sdn. Bhd.	MDA-2377-WDP121
29 March 2022	MDA/PMSV/R2022-018	Voluntary recall	In.Pact Admiral Paclitaxel-Eluting PTA Balloon Catheter	GD42436494017	Class III	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.