MEDICAL DEVICE RECALL LISTING

JANUARY 2022

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
10/1/2022	MDA/PMSV/R2022-001	Voluntary Recall	1688 4K Camera Control Unit with Advanced Imaging Modality	GA1026461936035	Class III	A21 Labelling, Instructions for Use or Training Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
11/1/2021	MDA/PMSV/R2022-002	Voluntary Recall	NobelReplace CC RP 4.3x11.5 mm	GC95763250017	Class II	A05 Mechanical Problem	Kavo Kerr Group Malaysia Sdn. Bhd.	MDA-818-D69815
11/1/2021	MDA/PMSV/R2022-003	Voluntary Recall	AGILON® Glenoid Cementless	GC938121294519	Class III	A02 Manufacturing, Packaging or Shipping Problem	ENRICH MEDSURG SDN BHD	MDA-1520-W120
19/1/2021	MDA/PMSV/R2022-004	Voluntary Recall	Biolox® delta Ceramic V40™ Femoral Head 32/ -4.0mm (6570-0-032) Biolox® delta Ceramic V40™ Femoral Head 36/ +0.0mm (6570-0-136)	GD83312836918 GC48361787918 GC23592916318	Class III	A21 Labelling, Instructions for Use or	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515

			Biolox® delta Ceramic V40™ Femoral Head 32/ +4.0mm (6570-0-232)			Training Problem		
25/1/2021	MDA/PMSV/ R2022-005	Voluntary Recall	ADVANIX BILIARY STENT WITH NAVIFLEX RX DELIVERY SYSTEM	GC18985179017	Class III	A25 No Apparent Adverse Event	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315
28/1/2021	MDA/PMSV/ R2022-006	Voluntary Recall	C315HIS Delivery Catheter	GD9853790221 8	Class II	A05 Mechanical Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
4/1/2021	MDA/PMSV/ R2022-007	Voluntary Recall	CrAg® LFA	IVDC466851410 18	Class II	A09 Output Problem	All Eights (M) Sdn Bhd	MDA-0037-WDP3714

** 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.*