MEDICAL DEVICE RECALL LISTING

JANUARY 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
21/1/2021	MDA/PMSV/R2021-001	Voluntary Recall	Polypectomy Snares (Captiflex, Captivator, Captivator II, Profile, Sensation)	GB7742858216	Class II	A16 Protective Measures Problem	Boston Scientific (M) Sdn Bhd	MDA-1754-WDP121
25/1/2021	MDA/PMSV/R2021-002	Voluntary Recall	Revigance Lift Sterile PDO (Polydioxanone) Suture With Needle	GD10838319-27082	Class III	A04 Material Integrity Problem	AJ Research & Pharma Sdn. Bhd.	MDA-2480-WDP121

** 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.*

MEDICAL DEVICE RECALL LISTING

FEBRUARY 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
2/2/2021	MDA/PMSV/ R2021-003	Voluntary Recall	Insulin Syringe	GB83427168517	Class II	A08 Calibration Problem	Ideal Healthcare Sdn Bhd	MDA-0003-KD314
3/2/2021	MDA/PMSV/ R2021-004	Voluntary Recall	Tecnis Toric 1-Piece Acrylic Intraocular Lens	GC62178188817	Class III	A23 Use of Device Problem	Johnson & Johnson Sdn. Bhd.	MDA-0081-WDP415
15/2/2021	MDA/PMSV/ R2021-005	Voluntary Recall	Valiant Navion™ Thoracic Stent Graft System	GD8644419-29954	Class I	A24 Adverse Event Without Identified Device or Use Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
18/2/2021	MDA/PMSV/ R2021-006	Voluntary Recall	Alinity i HIV Ag/Ab Combo Calibrator	IVDD45413228618	Class I	A21 Labelling, Instructions for Use or Training Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121

18/2/2021	MDA/PMSV/R2021-007	Voluntary Recall	Disposable Syringe 50 ml Luer Lock & Disposable Syringe 50 ml Luer Slip	GA8289892816	Class II	A18 Contiminatio n/ decontiminat ion problem	Muzamal Industries Sdn Bhd	MDA-0934-K120
22/2/2021	MDA/PMSV/R2021-008	Voluntary Recall	DC Bead™, DC Bead™ M1, and DC Bead LUMI™ Radiopaque Microspheres	GD5459620-41507	Class III	A21 Labelling, Instructions for Use or Training Problem	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315
24/2/2021	MDA/PMSV/R2021-009	Voluntary Recall	Amicus Seperator	GC61175798418	Class II	A05 Mechanical Problem	Fresenius Kabi Malaysia Sdn. Bhd.	MDA-1185-WP120
25/2/2021	MDA/PMSV/R2021-010	Voluntary Recall	Triathlon Tritanium Tibial Component, Size 4	GD4222261161 8	Class III	A02 Manufacturin g, Packaging or Shipping Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
26/2/2021	MDA/PMSV/R2021-011	Voluntary Recall	Implacross® PE Insert 10°Ø 28/35mm	GC5835819-32229	Class III	A04 Material Integrity Problem	Enrich Medsurg Sdn Bhd	MDA-1520-W120
27/2/2021	MDA/PMSV/R2021-012	Voluntary Recall	Thermo Scientific™ VersaTREK™ Automated Microbial detection System SBC Software 2.0.2.2	Special access	Class III	A11 Computer Software Problem	Thermo Scientific Microbiology Sdn. Bhd.	KP9537878115

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MEDICAL DEVICE RECALL LISTING

MARCH 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
11/3/2021	MDA/PMSV/ R2021-013	Voluntary Recall	Surgiwand II Suction And Irrigation Device	GB54028806418	Class II	A02 Manufacturing, Packaging or Shipping Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
11/3/2021	MDA/PMSV/ R2021-014	Voluntary Recall	Arrow® OnConrol® Bone Lesion Biopsy System Tray	GB81172407517	Class II	A05 Mechanical Problem	Teleflex Medical Sdn Bhd	MDA-912-W78115
12/3/2021	MDA/PMSV/ R2021-015	Voluntary Recall	Video processor/illuminator (VPI)	GB9703519-3597, GB9913119-35970	Class II	A11 Computer Software Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
18/3/2021	MDA/PMSV/ R2021-016	Voluntary Recall	Gravity Infusion sets & connectors	GB98684803818 GMD5708728216A GB46910936618 GA12081131417	Class II	A04 Material Integrity Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314

30/3/2021	MDA/PMSV/ R2021-017	Voluntary Recall	Alcohol Swab	GA2186420-38592	Class III	A02 Manufacturing, Packaging or Shipping Problem	Sun Healthcare (M) Sdn Bhd	MDA-0526-K52619
30/3/2021	MDA/PMSV/ R2021-018	Voluntary Recall	Tubing Set, Irrigation, PC	GC369381061518	Class III	A02 Manufacturing, Packaging or Shipping Problem	UMMI Surgical Sdn Bhd	MDA-163-WDP7515
30/3/2021	MDA/PMSV/ R2021-019	Voluntary Recall	HYSTEROMAT E.A.S.I.®	GC387141125118	Class III	A06 Output Problem	UMMI Surgical Sdn Bhd	MDA-163-WDP7515
30/3/2021	MDA/PMSV/ R2021-020	Voluntary Recall	HYSTOACRYL BLUE 0.5ML	GD689037231118	Class III	A03 Chemical Problem	Apex Pharmacy Marketing Sdn Bhd	MDA-1201-WDP120

** 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.*

MEDICAL DEVICE RECALL LISTING

APRIL 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
7/4/2021	MDA/PMSV/R2021-021	Voluntary Recall	ARCHITECT HBsAg Next Confirmatory Reagent Kit	IVDD3213419-36000	Class II	A09 Output Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121
7/4/2021	MDA/PMSV/R2021-022	Voluntary Recall	Gunther Tulip® Vena Cava Filter Retrieval Set for Jugular Vein Approach (RPN: GTRS-200-RB)	GD997621116318	Class I	A02 Manufacturing, Packaging or Shipping Problem	Cook Asia (Malaysia) Sdn Bhd	MDA-497-WDP40015
8/4/2021	MDA/PMSV/R2021-023	Voluntary Recall	10mm x 32cm Regular (Vented) Suction Irrigator Tip 10mm x 32cm Pool Suction Irrigator Tip 5mm x 32cm Regular (Vented) Sution Irrigator Tip 5mm x 32cm Pool Suction Irrigator Tip	GC182861046218, GC36399916518	Class III	A18 Contimination/ decontimination problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515

			5mm x 33cm Monopolar Handle 5mm x 33cm Ratcheting Handle					
7/4/2021	MDA/PMSV/R2021-024	Voluntary Recall	Resolution Clip Device	GC99352258317	Class III	A21 Labelling, Instructions for Use or Training Problem	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315
14/4/2021	MDA/PMSV/R2021-025	Voluntary Recall	Gunther Tulip® Vena Cava Filter Retrieval Set for Jugular Vein Approach (RPN: GTRS-200-RB)	GD997621116318	Class III	A02 Manufacturing, Packaging or Shipping Problem	Syarikat Perniagaan Miscell Sdn. Bhd.	MDA-1642-DP121
19/4/2021	MDA/PMSV/R2021-026	Voluntary Recall	Omnia Soft Tissue Punch	GB26021446717	Class III	A02 Manufacturing, Packaging or Shipping Problem	Kavo Kerr Group Malaysia Sdn. Bhd.	MDA-818-D69815
20/4/2021	MDA/PMSV/R2021-027	Voluntary Recall	BD Microtainer EDTA Tubes	IVDB14372247818	Class III	A02 Manufacturing, Packaging or Shipping Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314
22/4/2021	MDA/PMSV/R2021-028	Voluntary Recall	Eluvia Drug-Eluting Vascular Stent System	GD898551863 17	Class III	A21 Labelling, Instructions	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315

						for Use or Training Problem		

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MEDICAL DEVICE RECALL LISTING

MAY 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
3/5/2021	MDA/PMSV/R2021-029	Voluntary Recall	RUSCHELIT@ Super Safety Clear Tracheal Tube	GB87665877718	Class II	A05 Mechanical Problem	Teleflex Medical Sdn Bhd.	MDA-912-W78115
6/5/2021	MDA/PMSV/R2021-030	Voluntary Recall	ACUVUE® Vita® Brand Contact Lenses	GB73488352217	Class III	A02 Manufacturing, Packaging or Shipping Problem	Johnson & Johnson Sdn. Bhd.	MDA-0081-WDP415
6/5/2021	MDA/PMSV/R2021-031	Voluntary Recall	ARIES® HSV 1&2 Assay	IVDC44297287118	Class III	A02 Manufacturing, Packaging or Shipping Problem	DKSH Malaysia Sdn. Bhd.	MDA-0023-WDP2314
11/5/2021	MDA/PMSV/R2021-032	Voluntary Recall	BD Venflon Pro Safety Needle Protected I.V. Cannula	GB223681152118	Class III	A16 Protective Measures Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314

17/5/2021	MDA/PMSV/ R2021-033	Voluntary Recall	Synaptive™ Trackable Suction	GB10651620-44306	Class III	A05 Mechanical Problem	Transmedic Healthcare Sdn Bhd	MDA-096-WDP1815
18/5/2021	MDA/PMSV/ R2021-034	Voluntary Recall	Mako Hip End Effector, Variable Angle	GC593731188118	Class III	A05 Mechanical Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
19/5/2021	MDA/PMSV/ R2021-035	Voluntary Recall	ARCHITECT 2nd Generation Testosterone Reagent Kit	IVDB31560272718	Class III	A09 Output Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121
21/5/2021	MDA/PMSV/ R2021-036	Voluntary Recall	Video Mediastinoscope	GB5350019-30371	Class I	A02 Manufacturing, Packaging or Shipping Problem	UMMI Surgical Sdn Bhd	MDA-163-WDP7515
22/5/2021	MDA/PMSV/ R2021-037	Voluntary Recall	Arrow® - FiberOptix™ Intra-Aortic Balloon (IAB) Catheter Kit Ultra 8 IAB (IAB-05840-U)	GD444147011118 & GD877091305219	Class III	A02 Manufacturing, Packaging or Shipping Problem	Teleflex Medical Sdn Bhd	MDA-912-W78115
27/5/2021	MDA/PMSV/ R2021-038	Voluntary Recall	Filter,Insufflation	GC15073992218	Class II	A18 Contimination/ decontimination problem	UMMI Surgical Sdn Bhd	MDA-163-WDP7515

27/5/2021	MDA/PMSV/R2021-039	Voluntary Recall	Venovo Venous Stent System	GD3171320-44431	Class II	A02 Manufacturing, Packaging or Shipping Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314
28/5/2021	MDA/PMSV/R2021-040	Voluntary Recall	Covidien DAR™ airway products	GA81947176117 GMD95474341017 GB64574504517 GB38078774718 GB25845805318 GB44241838118 GB26726858518 GB68839860018 GB24250871218 GB49821974018	Class III	A18 Contiminati on/ decontimin ation problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
31/5/2021	MDA/PMSV/R2021-041	Voluntary Recall	Sarns™ TCM II Cooling and Heating Systems	Orphan Medical Device	Class III	A18 Contiminati on/ decontimin ation problem	Terumo Malaysia Sdn. Bhd.	MDA-0794-WDP120

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MEDICAL DEVICE RECALL LISTING

JUNE 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
31/5/2021	MDA/PMSV/R2021-042	Voluntary Recall	Transport Stretcher Prime Series with 5th wheel Stretcher (26 inch) Prime X Series with 5th wheel stretcher option Prime Series with big wheel Stretcher (30 inch) Bed InTouch without Zoom motor Secure 3 MedSurg Bed S3 EX – 3005 Stretcher Chair ST1-X Transport Stretcher SV1 Electric Hospital Bed SV2 Electric Hospital Bed	GMD81312423118A GA3888881016 GA94134878118 GMD52758479818A GMD24596367817A GA6897520-38646 GMD56953688518A GMD24011639518A	Class III	A23 Use of Device Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
1/6/2021	MDA/PMSV/R2021-043	Voluntary Recall	ZNN CMN Nail Comingle	GC272951021218	Class III	A02 Manufacturing,	Zimmer Medical (M) Sdn Bhd	MDA-0074-WDP7419

						Packaging or Shipping Problem		
2/6/2021	MDA/PMSV/R2021-044	Voluntary Recall	Accessory 924256 Stimloc Burr Hole Cover 17L	GD956622070 17	Class II	A02 Manufacturing, Packaging or Shipping Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
3/6/2021	MDA/PMSV/R2021-045	Voluntary Recall	Palindrome RT Chronic Catheter Kit	GD458023887 17	Class II	A21 Labelling, Instructions for Use or Training Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
4/6/2021	MDA/PMSV/R2021-046	Voluntary Recall	PD 3L EMPTY BAG SYSTEM II	GA3899376816	Class III	A02 Manufacturing, Packaging or Shipping Problem	Baxter Healthcare (Malaysia) Sdn. Bhd	MDA-1025-WDP120
9/6/2021	MDA/PMSV/R2021-047	Voluntary Recall	JELONET Paraffin Gauze Dressing	GB1368175916	Class III	A02 Manufacturing, Packaging or Shipping Problem	Smith & Nephew Healthcare Sdn Berhad	MDA-00350-WP3514
14/6/2021	MDA/PMSV/R2021-048	Voluntary Recall	CoreValve Evolut R System	GD682501280619	Class II	A05 Mechanical Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414

			CoreValve Evolut Pro System	GD93060896418				
18/6/2021	MDA/PMSV/R2021-049	Voluntary Recall	Bare Fiber Single Use Sterile	GB87163763218	Class II	A18 Contimination/ decontimination problem	Biolitec (M) Sdn Bhd	MDA-1470-WDP120
29/6/2021	MDA/PMSV/R2021-050	Voluntary Recall	EMBLEM S-ICD System	GD51274167517	Class III	A05 Mechanical Problem	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315
11/6/2021	MDA/PMSV/R2021-051	Voluntary Recall	Trilogy 100 Trilogy 200 A-Series BiPAP A40 A-Series BiPAP A30	GC68672225217 GC35643583518	Class II	A04 Material Integrity Problem	Philips Malaysia Sdn Bhd	MDA-0061-WDP6114
11/6/2021	MDA/PMSV/R2021-052	Voluntary Recall	DreamStation ASV DreamStation ST, AVAPS SystemOne ASV4 C-Series ASV C-Series S/T and AVAPS OmniLab Advanced+ SystemOne (Q-Series) DreamStation DreamStation Go Dorma 400 Dorma 500	GC68672225217 GC35643583518	Class II	A04 Material Integrity Problem	Philips Malaysia Sdn Bhd	MDA-0061-WDP6114

17/6/2021	MDA/PMSV/R2021-053	Voluntary Recall	Custom-Pak: MAL-Basic Cataract Pack (THONEH)	GC91293930918	Class II	A02 Manufacturing, Packaging or Shipping Problem	Alcon Laboratories Sdn Bhd	MDA-2114-W121

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MEDICAL DEVICE RECALL LISTING

JULY 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
1/7/2021	MDA/PMSV/R2021-054	Voluntary Recall	HIGHFLEX Basket	GB67531725318	Class II	A02 Manufacturing, Packaging or Shipping Problem	UMMI Surgical Sdn.Bhd	MDA-163-WDP7515
6/7/2021	MDA/PMSV/R2021-055	Voluntary Recall	TRIATHLON PRIM CEM FXD BPLT #7 (STRYKER TRIATHLON TOTAL KNEE REPLACEMENT SYSTEM)	GD42222611618	Class III	A02 Manufacturing, Packaging or Shipping Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
7/7/2021	MDA/PMSV/R2021-056	Voluntary Recall	Heartware Ventricular Assist System (HVAD)	GD74345985518	Class I	A05 Mechanical Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
8/7/2021	MDA/PMSV/R2021-057	Voluntary Recall	High Flex Baskets	GB67531725318	Class II	A02 Manufacturing, Packaging	Becton Dickinson Sdn Bhd	MDA-0033-W3314

						or Shipping Problem		
9/7/2021	MDA/PMSV/R2021-058	Voluntary Recall	Restoris MCK Femoral Trial Restoris MCK Patellofemoral Trial	GC593731188118 GC91928491317	Class III	A02 Manufacturing, Packaging or Shipping Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
21/7/2021	MDA/PMSV/R2021-059	Voluntary Recall	Frova Intubating Introducer (RPN: C-CAE-14.0-70-FI)	GD997621116318	Class II	A02 Manufacturing, Packaging or Shipping Problem	Cook Asia (Malaysia) Sdn Bhd	MDA-497-WDP40015
21/7/2021	MDA/PMSV/R2021-060	Voluntary Recall	Pipeline™ Flex Embolization Device Pipeline™ Flex Embolization Device with Shield Technology™	GD994342033117 GD241044953117	Class II	A02 Manufacturing, Packaging or Shipping Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
22/7/2021	MDA/PMSV/R2021-061	Voluntary Recall	HARMONIC HD 1000I SHEARS 20CM SHAFT HARMONIC HD 1000I SHEARS 36CM SHAFT	GC34335374217	Class II	A05 Mechanical Problem	Johnson & Johnson Sdn. Bhd.	MDA-0081-WDP415
27/7/2021	MDA/PMSV/R2021-062	Voluntary Recall	UNICORE	GB71343205817	Class III	A02 Manufacturing,	Healthcare Solution Sdn Bhd	MDA-2161-W121

			(UNICORE, MEDAX FINE NEEDLE ASPIRATION, EPITHEASY)			Packaging or Shipping Problem		

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MEDICAL DEVICE RECALL LISTING

AUGUST 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
2/8/2021	MDA/PMSV/ R2021-063	Voluntary Recall	Arcos Modular Revision System	GC28127102171 8	Class II	A02 Manufactur ing, Packaging or Shipping Problem	Zimmer Medical (M) Sdn Bhd	MDA-0074-WDP7419
2/8/2021	MDA/PMSV/ R2021-064	Voluntary Recall	DUODERM EXTRA THIN CGF DRESSING DUODERM™ CGF™ CONTROL GEL FORMULA DRESSING	GD3783421511 7 GD3191610246 18	Class III	A02 Manufactur ing, Packaging or Shipping Problem	ConvaTec Malaysia Sdn Bhd	MDA-1913-W121
3/8/2021	MDA/PMSV/ R2021-065	Voluntary Recall	PRISMAFLEX M100 SET	GC99624912318	Class III	A02 Manufactur ing, Packaging or Shipping Problem	Baxter Healthcare (Malaysia) Sdn. Bhd	MDA-1025-WDP120

6/8/2021	MDA/PMSV/ R2021-066	Voluntary Recall	STEELEX® STE SET	GC28167528118	Class III	A02 Manufacturing, Packaging or Shipping Problem	B. Braun Medical Supplies Sdn Bhd	MDA-0032-DP3214
12/8/2021	MDA/PMSV/ R2021-067	Voluntary Recall	Percuflex Plus Ureteral Stent	GC72146322617	Class III	A02 Manufacturing, Packaging or Shipping Problem	Boston Scientific (M) Sdn Bhd	MDA-138-WDP5315
20/8/2021	MDA/PMSV/ R2021-068	Voluntary Recall	Illinois Bone Marrow Aspiration/Intraosseous Infusion Needle 15G x 79mm	GB45267961418	Class II	A02 Manufacturing, Packaging or Shipping Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314
23/8/2021	MDA/PMSV/ R2021-069	Voluntary Recall	DLP Left Heart Vent Catheters	GB73074946118	Class II	A05 Mechanical Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414

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MEDICAL DEVICE RECALL LISTING

SEPTEMBER 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
1/9/2021	MDA/PMSV/R2021-070	Voluntary Recall	Sterile Blade Single-Use Accessories	GB51997858318 GB58828845718	Class II	A05 Mechanical Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
6/9/2021	MDA/PMSV/R2021-071	Voluntary Recall	EcoGel 200/ MediChoice Ultrasound Gel	GMD78847317617A	Class III	A18 Contimination/ decontimination problem	Somedico Sdn. Bhd.	MDA-1824-WDP121
13/9/2021	MDA/PMSV/R2021-072	Voluntary Recall	10mm CPCS Distal Centralizers	GC67108823418	Class III	A04 Material Integrity Problem	Smith & Nephew Healthcare Sdn Berhad	MDA-00350-WP3514
24/9/2021	MDA/PMSV/R2021-073	Voluntary Recall	Ilizarov Wire Tensioner	GC43867914218	Class III	A02 Manufacturing, Packaging or Shipping Problem	Smith & Nephew Healthcare Sdn Berhad	MDA-00350-WP3514

29/9/2021	MDA/PMSV/R2021-074	Voluntary Recall	Sterile Blade Single-Use Accessories	GD997621116318	Class III	A16 Protective Measures Problem	Syarikat Perniagaan Miscell Sdn. Bhd.	MDA-1642-DP121

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MEDICAL DEVICE RECALL LISTING

OCTOBER 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
6/10/2021	MDA/PMSV/R2021-075	Voluntary Recall	FIVE S 3.5x65, sterile, for single use	GB5838321-52999	Class II	A02 Manufacturing, Packaging or Shipping Problem	UMMI Surgical Sdn Bhd	MDA-163-WDP7515

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MEDICAL DEVICE RECALL LISTING

NOVEMBER 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
1/11/2021	MDA/PMSV/R2021-076	Field Corrective Action	Intravascular Temperature Management System (IVTM)	GD36871341117	Class I	A05 Mechanical Problem	Zoll Medical Malaysia Sdn. Bhd.	MDA-925-WDP79215
3/11/2021	MDA/PMSV/R2021-077	Voluntary Recall	Drill, AO small Gamma3® Ø4.2 x 300 mm	GC32996796918	Class III	A02 Manufacturing, Packaging or Shipping Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
3/11/2021	MDA/PMSV/R2021-078	Voluntary Recall	Lifespan Eptfe Vascular Graft	GD222688102118	Class III	A02 Manufacturing, Packaging or Shipping Problem	Nyprax Business Solutions	MDA-400-WDP30415
10/11/2021	MDA/PMSV/R2021-079	Voluntary Recall	28MM -4 LFIT V40 HEAD (6260-9-028)	GC23592916318	Class III	A02 Manufacturing, Packaging	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515

			22.2MM STD LFIT V40 HEAD (6260-9-122)			or Shipping Problem		
12/11/2021	MDA/PMSV/R2021-080	Voluntary Recall	Avelle™ Negative Pressure Wound Therapy (NPWT) Pump22.2MM STD LFIT V40 HEAD (6260-9-122)	GC78842764418	Class III	A02 Manufacturing, Packaging or Shipping Problem	ConvaTec Malaysia Sdn Bhd	MDA-1913-W121
15/11/2021	MDA/PMSV/R2021-081	Voluntary Recall	ARCHITECT Trigger Solution	IVDA11021198618	Class III	A21 Labelling, Instructions for Use or Training Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121
17/11/2021	MDA/PMSV/R2021-082	Voluntary Recall	3M Nexcare Tegaderm Transparent Dressing (H1626)	GB81651211117	Class III	A21 Labelling, Instructions for Use or Training Problem	Delfi Marketing Sdn. Bhd.	MDA-1077-WDP120
26/11/2021	MDA/PMSV/R2021-083	Voluntary Recall	DRILL FOR 5MM, 1.5 x 50MM, STRYKER-SHAFT	GC15618916118	Class III	A02 Manufacturing, Packaging or Shipping Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515

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MEDICAL DEVICE RECALL LISTING

DECEMBER 2021

Date Received	Ref. No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
13/12/2021	MDA/PMSV/R2021-084	Field Corrective Action	BD Vacutainer® ACD Solution A Blood Collection Tubes	IVDB34161212418	Class II	A02 Manufacturing, Packaging or Shipping Problem	Becton Dickinson Sdn Bhd	MDA-0033-W3314
16/12/2021	MDA/PMSV/R2021-085	Voluntary Recall	Dynetic-35	GD5342320-50549	Class II	A18 Contimination/ decontimination problem	Biotronik Medical Devices (Malaysia) Sdn. Bhd	MDA-2134-WDP121
20/12/2021	MDA/PMSV/R2021-086	Voluntary Recall	Multichem WBT	IVDC53568227818	Class III	A21 Labelling, Instructions for Use or Training Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121

20/12/2021	MDA/PMSV/R2021-087	Voluntary Recall	VIZADISC Hip Procedure Tracking Kit VIZADISC Knee Procedure Tracking Kit	GC593731188118	Class III	A21 Labelling, Instructions for Use or Training Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-542-WDP44515
23/12/2021	MDA/PMSV/R2021-088	Voluntary Recall	NIM TriVantage EMG Endotracheal Tube NIM-Neuro 3.0 System and Accessories	GB91582260417 GB45802845818	Class II	A02 Manufacturing, Packaging or Shipping Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414
22/12/2021	MDA/PMSV/R2021-089	Voluntary Recall	Disposable Subdermal Corkscrew Needle Electrode	GB748191272819	Class III	A21 Labelling, Instructions for Use or Training Problem	Abbott Laboratories (M) Sdn. Bhd.	MDA-1685-W121
23/12/2021	MDA/PMSV/R2021-090	Voluntary Recall	All non-implanted Oticon Medical Neuro Zti EVO implants with a serial number from NZB04074 and above,	GD71157688718	Class III	A17 Compatibility Problem	Demant Malaysia Sdn. Bhd.	MDA-1624-WDP121

			All non-implanted Oticon Medical Neuro Zti CLA implants with a serial number from NZA02454 and above.					
27/12/2021	MDA/PMSV/R20 21-091	Voluntary Recall	Endurant II and Endurant IIS Stent Graft System	GD23961629218	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.*