



MEDICAL DEVICE RECALL LISTING JUNE 2022

Date Received	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
31 May 2022	MDA/PMSV/R2022-028	Voluntary Recall	Nucleus 7 Processing Unit (CP1000) - Black, Platinum Detail	GC858411305719	Class III	A07: Electrical /Electronic Property Problem	Cochlear Malaysia Sdn Bhd	MDA-824-W70415
1 June 2022	MDA/PMSV/R2022-029	Voluntary Recall	Parallel plate applicators for CoolSculpting	GB59450175217	Class III	A24: Adverse Event Without Identified Device or Use Problem	Allergan Malaysia Sdn Bhd	MDA-1461-W120
6 June 2022	MDA/PMSV/R2022-030	Voluntary Recall	- Triathlon Solid Cr Tibial Insert Trial Size 2 - 9mm (5530-T-209y) Lot: A234p - Triathlon Solid Cr Tibial Insert Trial Size 2 - 10mm (5530-T-210y) Lot: A234q	GD42222611618		A21: Labelling, Instructions for Use or Training Problem	Stryker Corporation (Malaysia) Sdn Bhd	MDA-2123-WDP121
14 June 2022	MDA/PMSV/R2022-031	Voluntary Recall	1. Mahurkar Chronic Carbothane Catheter Kit 2. Palindrome Chronic Catheter Kit 3. Palindrome H Chronic Catheter Kit 4. Palindrome HSI Chronic Catheter Kit 5. Palindrome SI Chronic Catheter	1. GD64605629118 2. GD31135554618 3. GD92330689518 4. GD54204598918 5. GD99473820318	Class II	A02: Manufacturing, Packaging or Shipping Problem	Medtronic Malaysia Sdn Bhd	MDA-0074-WDP7414



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20 June 2022	MDA/PMSV/R2022-032	Voluntary Recall	DOG1 (SP31) Rabbit Monoclonal Antibody	IVDB87950214718	Class II	-	Roche Diagnostics (M) Sdn Bhd	MDA-1674-WDP121
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* 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.