MEDICAL DEVICE RECALL LISTING FEBRUARY 2022

Date Received	Reference No.	Recall Type	Product Name	Product Registration	Recall Class	Reason of Recall	Recalling Establishment	Establishment License
3 February 2022	MDA/PSV/R2022-009	Voluntary recall	2.5 mm and 3.5 mm Prevail Paclitaxel-coated PTCA Balloon Catheter (Prevail catheter)	GD9712721-75150	Class II	A21: Labelling, Instruction of use or Training Problems	Medtronic Malaysia Sdn. Bhd.	MDA-0074-WDP7414
22 February 2022	MDA/PMSV/R2022-010	Voluntary recall	LiquiBand Fix8 Open Hernia Mesh Fixation device (FX002)	GC10940220-45817	Class III	A05: Mechanical Problem	Advanced Medical Solutions Ltd	MDA-1160-WDP120
28 February 2022	MDA/PMSV/R2022-011	Voluntary recall	2.5 mm and 3.5 mm Prevail Paclitaxel-coated PTCA Balloon Catheter (Prevail catheter)	GC32354730618 GC946181006118 GC51059813518	Class III	A04: Material Integrity Problem	Affluent Healthcare Sdn. Bhd.	MDA-3072-WDP121
8 February 2022	MDA/PMSV/R2022-012	Voluntary recall	1688 Pendulum Camera Head with Integrated Coupler	GA1026461936035	Class III	A11: Computer software problem	Stryker Corporation (Malaysia) Sdn. Bhd.	MDA-542-WDP44515

* 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.