

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING JUNE 2026

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	02/06/2026	1.5cm Spherical Applicators for INTRABEAM (Reference: FCA_OKO_2026_001 IORT Non-Conformance in Batch Release of 1.5cm Spherical Applicators)	INTRABEAM 600	MDA/FCA/P1808-59002357-2026	GD779388116	CARL ZEISS SDN BHD siao-yi.won@zeiss.com
2	03/06/2026	Canopy Soffits and fasteners on Giraffe OmniBed and Giraffe OmniBed Carestation Devices GIRAFFE OMNIBED CARESTATION CS1 (GC36600486117)	GIRAFFE OMNIBED CARESTATION CS1	MDA/FCA/P1809-97527495-2026	GC36600486117	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
3	03/06/2026	AW Server 3.2 ext. 6.5 – Potential Patient Context Synchronization Issue AW SERVER 3.2 (GB3800423-134964)	AW SERVER 3.2	MDA/FCA/P1810-56292898-2026	GB3800423-134964	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
4	05/06/2026	FA1567 Rev A Bio-Medicus™ Adult Cannula Kit Potential Contaminated product	BIO-MEDICUS™ FEMORAL PERCUTANEOUS CANNULA KIT	MDA/FCA/P1813-21800481-2026	GB2264623-129875	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
5	08/06/2026	ELLA-CS, s.r.o. initiates voluntary Field Safety Corrective Action concerning the products Danis Procedure Pack – Basic and Danis Procedure Pack	SX-ELLA STENT DANIS (DANIS STENT)	MDA/FCA/P1817-21414090-2026	GC2594924-183987	VITRAMED MALAYSIA SDN. BHD.
6	09/06/2026	2025-PD-MR-011 MR systems with SW versions R11.1 and R12.1 MobiView cross reference alignment errors	MR 5300	MDA/FCA/P1821-74936737-2026	GB2458922-104130	PHILIPS MALAYSIA SENDIRIAN BERHAD shirenn.tiam@philips.com

7	10/06/2026	037 FSAC AHC 26-06 Atellica CH Enzymatic Hemoglobin A1c (A1c_E) Potential for Well-to-Well Shifts Impacting Atellica CH A1c_E	ATELLICA® CH ENZYMATIC HEMOGLOBIN A1C (A1C_E)	MDA/FCA/P1827-37124656-2026	IVDB9845619-35149	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
8	12/06/2026	Polyaxial & reduction screwdriver assembly - functional defect on the threaded part	VEOS	MDA/FCA/P1829-86433162-2026	GC7424624-168464	SYNERGIC EVOLUTION SDN BHD info@synergicevo.com
9	12/06/2026	2026-CC-HPM-001 - Philips Avalon Fetal Monitor Incorrect Assembly of Speaker Connector	AVALON FETAL MONITORS	MDA/FCA/P1830-56498278-2026	GC95268545118	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
10	15/06/2026	Notice of Revision to LCMS CLAM-2030 CL Specification Wording.	Fully Automated Sample Preparation Module for LCMS	MDA/FCA/P1831-15789112-2026	IVDA7288821-81276	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
11	15/06/2026	Olympus to Provide Offset Adjustment for UHI-4 Pressure Sensors	HIGH FLOW INSUFFLATION UNIT	MDA/FCA/P1833-61175442-2026	GB929511113418	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
12	16/06/2026	Urgent Medical Device Recall (Correction): Potential Introducer Sheath Leakage in Impella Introducer Kits (14Fr and 23Fr) Used with Impella Heart Pumps	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1834-57449488-2026	GD9474523-140294	DCH AURIGA (M) SDN BHD LimLiangJun@dchauriga.com
13	18/06/2026	Customer Advisory Notice CT018/25/P - Incorrect DLP value displayed and recorded in DICOM data	SOMATOM X.CITE	MDA/FCA/P1835-27645955-2026	GC5563225-208447	SIEMENS HEALTHCARE SDN. BHD.
14	19/06/2026	FSAC- Oncomine™ Dx Express Test Panel	ONCOMINE DX EXPRESS TEST	MDA/FCA/P1837-45932587-2026	IVDC8307123-151995	BIOMARKETING SERVICES (M) SDN BHD regulatory.my@biomedglobal.com
15	23/06/2026	2025-IGT-BST-018 Philips Azurion Potential loss of imaging functionality due to unauthorized Hard Disk Drives	AZURION 7	MDA/FCA/P1840-55348095-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com

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16	23/06/2026	2025-IGT-BST-018 Philips Azurion Potential loss of imaging functionality due to unauthorized Hard Disk Drives	AZURION BIPLANE	MDA/FCA/P1841- 57191580-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
17	24/06/2026	Astral 100/150 – Ventilator may stop delivering therapy due to internal component issue	ASTRAL	MDA/FCA/P1842- 59923086-2026	GC65216272017	RESMED MALAYSIA OPERATIONS SDN. BHD.
18	25/06/2026	Advice on Instructions for Use (IFU) for the AirSeal® Access Ports	AIRSEAL® IFS INTELLIGENT FLOW SYSTEM	MDA/FCA/P1847- 10842414-2026	GB5554822-110272	MEDI-LIFE (M) SDN. BHD.
19	26/06/2026	EliA™ ANA Positive Control 250: Update to EliA Ro60 & EliA dsDNA Acceptance Range Information	ELIA METHOD SPECIFIC REAGENTS MARKER	MDA/FCA/P1848- 73460510-2026	IVDB10943324- 173555	BIOMARKETING SERVICES (M) SDN BHD regulatory.my@biomedglobal.com

* The information contained in the Medical Device Authority Field Corrective Action database is released under Regulation 7(8) and Regulation 8 (5) of Malaysia's Medical Device Regulations 2019.