



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING MARCH 2026

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	02/03/2026	2024-IGT-BST-026 - Philips Azurion potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.	AZURION 3	MDA/FCA/P1693-95365592-2026	GC99381544218	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
2	03/03/2026	2024-IGT-BST-026 - Philips Azurion potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.	AZURION 5	MDA/FCA/P1694-24420952-2026	GC10785320-48186	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
3	03/03/2026	2024-IGT-BST-026 - Philips Azurion potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.	AZURION 7	MDA/FCA/P1695-44042981-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
4	03/03/2026	2024-IGT-BST-026 - Philips Azurion potential loss of imaging functionality resulting from no or intermittent X-ray radiation initiation through the wired foot switch.	AZURION BIPLANE	MDA/FCA/P1696-32986984-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
5	04/03/2026	Field Corrective Action on Precipitates Forming in the Reconstitution Buffer within the Test Cartridge of Afinion HbA1c	AFINION HBA1C	MDA/FCA/P1697-28229741-2026	IVDB67848304818	ABBOTT DIAGNOSTICS HEALTH SDN BHD winnielinlin.hii@abbott.com
6	05/03/2026	2025-EI-RI-003 - Vue Motion V12 Potential for misdiagnosis due to multi-frame images displaying out of sequence	PHILIPS VUE PACS	MDA/FCA/P1699-68534877-2026	GB18651834218	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com

7	06/03/2026	Field Safety Corrective Action: Purge Cassette (Generation 1) for Impella System – Increased Risk of Purge Leak Leading to Low Purge Pressure	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1702-89676739-2026	GD9474523-140294	DCH AURIGA (M) SDN BHD LimLiangJun@dchauriga.com
8	13/03/2026	The value assignment of certain HemosIL Heparin Calibrator lots showed a bias against the WHO International Standards for UFH and LMWH, which could have resulted in reduced recovery when measuring heparin in controls and patient samples.	HEMOSIL LIQUID ANTI-XA	MDA/FCA/P1707-20692968-2026	IVDC53329234618	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
9	18/03/2026	Olympus to Remind Customers of HF Cable IFU Information.	ELECTROSURGICAL GENERATOR ESG-400	MDA/FCA/P1710-45933338-2026	GC94229142417	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
10	19/03/2026	FA1546 Induction of ventricular arrhythmia during Sphere-9™ catheter radiofrequency ablation in patients with Biotronik ICDs	AFFERA™ INTEGRATED MAPPING SYSTEM	MDA/FCA/P1712-31218074-2026	GD9452125-218019	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
11	24/03/2026	023 FSCA ACHC 26-05 Atellica CH Creatine Kinase (CK_L) Potential for Falsely Elevated Results with Lot Numbers 252591, 252602 and 252612	APELLICA® CH CREATINE KINASE (CK_L)	MDA/FCA/P1717-57493031-2026	IVDC9131423-128501	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
12	25/03/2026	024 CN AIMC 26-02 Atellica IM and ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Invalid Calibrations	APELLICA® IM FREE PROSTATE-SPECIFIC ANTIGEN (FPSA)	MDA/FCA/P1718-58514099-2026	IVDC82776266818	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
13	26/03/2026	Documentation Omission in LIAISON Rubella IgM, 310730 (Missing NFTU)	LIAISON® RUBELLA IGM	MDA/FCA/P1720-91186536-2026	IVDC8532923-128419	DIAGNOSTICARE SDN BHD zaidi.jantan@diagnosticare.com.my

14	26/03/2026	022 FSCA DC 26-01 Dimension Creatinine Flex Reagent Cartridge Imprecision with Quality Control and Patient Results for Dimension Creatinine Lot Numbers GA6307 and BA7005	DIMENSION CREATININE	MDA/FCA/P1721-13154273-2026	IVDB54125130718	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
15	27/03/2026	Software Anomaly Causing VITROS™ Systems to Switch From VITROS™ Calibrator Kit 32 to VITROS™ Calibrator Kit 2 During ADD Load	VITROS IMMUNODIAGNOSTIC PRODUCTS FERTILITY & PREGNANCY HORMONES & PROTEINS	MDA/FCA/P1725-75023993-2026	IVDB7258323-129195	T T MEDICAL MANAGEMENT SDN BHD ttcsdt05@gmail.com
16	27/03/2026	Reduced Shelf Life of PALAMIX® Mixing System	PALAMIX VACUUM MIXING SYSTEM	MDA/FCA/P1726-81262285-2026 (Attachment A) (Attachment B)	GB4398519-36101	ACX HEALTH SDN. BHD. regulatory.my@pharmatomarket.com
17	30/03/2026	2025-IGT-BST-025 Aneurysm Flow Potential Safety issue if MAFA ratio is used for clinical decision making	ANEURYSMFLOW	MDA/FCA/P1727-77143402-2026	GB16499497817	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
18	30/03/2026	To advise of updates to the Instructions for Use (IFU) to enhance the information for the users - Thoraflex Hybrid	THORAFLEX HYBRID DEVICE	MDA/FCA/P1728-11622190-2026	GD79535860718	TERUMO MALAYSIA SDN. BHD. TMSB_RAQ@terumo.co.jp

* 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.