

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING JULY 2026

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	01/07/2026	FA1546 Rev C - Wave 3 Induction of ventricular arrhythmia during Sphere-9™ catheter radiofrequency ablation in patients with Biotronik ICD/CRT-D Sphere-9™ Catheter	AFFERA™ INTEGRATED MAPPING SYSTEM	MDA/FCA/P1851-62017941-2026	GD9452125-218019	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
2	03/07/2026	EliA ANA Positive Control 200: Update to EliA La Acceptance Range Information	ELIA PHADIA 200 CONTROLS	MDA/FCA/P1853-93915629-2026	IVDB2265720-49554	BIOMARKETING SERVICES (M) SDN BHD regulatory.my@biomedglobal.com
3	07/07/2026	NOxBOXi Nitric Oxide Delivery Devices software update to V18.6		MDA/FCA/P1854-44083825-2026		SCHMIDT BIOMEDTECH SDN BHD faizah@schmidt bmt.com
4	06/07/2026	Field Corrective Action Report for Ø3.5 mm Cortical Screw (Product Code: 2040050, Lot No. 041925-09-V).	PLATE AND SCREW	MDA/FCA/P1855-76903506-2026	GC34418957118	OSA TECHNOLOGY SDN. BHD. hadry@osatechnology.com
5	08/07/2026	Resolution of software-related system responses (Patient Safe, Failsafe, false alarm) Software Update for the LEONI 4 Ventilator	LEONI VENTILATORS	MDA/FCA/P1857-85286905-2026	GC2172425-219272	SCHMIDT BIOMEDTECH SDN BHD faizah@schmidt bmt.com
6	10/07/2026	FSCA 041 CN 26-007 DCA Vantage HbA1c Atellica DCA HbA1c Monitor Kit DCA Vantage HbA1c HbA1c Reagent Cartridge Bias Issue due to Delamination	DCA VANTAGE SYSTEM	MDA/FCA/P1858-59061523-2026	IVDB8945423-128502	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
7	14/07/2026	Urine Meter (500ml) with 2000ml Drainage Bag have manufacturing defect	URINE METER 2000ML	MDA/FCA/P1861-58131711-2026	GMD76630876718A	FORESIGHT INDUSTRIES SDN BHD amirah@foresight.com.my

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING JULY 2026

8	24/07/2026	Possible delivery of a lower oxygen concentration than set - Oxylog 600		MDA/FCA/P1863-77633934-2026		DRAEGER MALAYSIA SDN BHD afrina.ramli.contractor@draeger.com
9	17/07/2026	UD-10: Inappropriate Assay Range of PCD_M for Recent UF-Control lots	Fully Automated Urine Particle Digital Imaging Device UD-10	MDA/FCA/P1864-52305113-2026	IVD7378939616A	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
10	21/07/2026	2026-IGT-BST-001 Philips Azurion R2.x.10 systems Potential image quality degradation and potential loss of geometry movement that may lead to delay of therapy, procedural complications, and/or inappropriate treatment.	AZURION 3	MDA/FCA/P1865-64805937-2026	GC99381544218	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
11	21/07/2026	2026-IGT-BST-001 Philips Azurion R2.x.10 systems Potential image quality degradation and potential loss of geometry movement that may lead to delay of therapy, procedural complications, and/or inappropriate treatment.	AZURION 5	MDA/FCA/P1867-12909917-2026	GC10785320-48186	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
12	21/07/2026	2026-IGT-BST-001 Philips Azurion R2.x.10 systems Potential image quality degradation and potential loss of geometry movement that may lead to delay of therapy, procedural complications, and/or inappropriate treatment.	AZURION 7	MDA/FCA/P1868-60142970-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com

13	21/07/2026	2026-IGT-BST-001 Philips Azurion R2.x.10 systems Potential image quality degradation and potential loss of geometry movement that may lead to delay of therapy, procedural complications, and/or inappropriate treatment. 4	AZURION BIPLANE	MDA/FCA/P1869-66579756-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
14	22/07/2026	FA-26022- Beckman Coulter has determined that a modification made by operators to 25 predefined calculated rules, which are included as part of the parameter package, will revert to the default expression following parameter package or software upgrades on the DxC 500i Clinical Analyzer and DxC 500 AU Clinical Chemistry Analyzer	DxC 500 AU Clinical Chemistry Analyzer	MDA/FCA/P1871-88606099-2026	IVDA3952124-168118	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
15	22/07/2026	FA-26022- Beckman Coulter has determined that a modification made by operators to 25 predefined calculated rules, which are included as part of the parameter package, will revert to the default expression following parameter package or software upgrades on the DxC 500i Clinical Analyzer and DxC 500 AU Clinical Chemistry Analyzer.	DxC 500i AU Chemistry Module	MDA/FCA/P1872-10772340-2026	IVDA8913224-171351	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING JULY 2026

16	23/07/2026	2025-IGT-BST-014 Philips Azurion R3.1 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement may result in a delay or termination of procedure	AZURION BIPLANE	MDA/FCA/P1874-94285514-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
17	23/07/2026	2025-IGT-BST-014 Philips Azurion R3.1 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement may result in a delay or termination of procedure	AZURION 5	MDA/FCA/P1875-51651556-2026	GC10785320-48186	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
18	23/07/2026	2025-IGT-BST-014 Philips Azurion R3.1 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement may result in a delay or termination of procedure	AZURION 7	MDA/FCA/P1876-51985796-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
19	23/07/2026	Specific Advice to inform Users, Importers, and Distributors about a discrepancy in the Synthetic Vascular Graft labeling concerning magnetic resonance (MR) compatibility.	SYNTHETIC VASCULAR GRAFT	MDA/FCA/P1880-43416624-2026	GD9447824-189842	B. BRAUN MEDICAL INDUSTRIES SDN. BHD. langfah.quek@bbraun.com
20	23/07/2026	Urgent Field Safety Notice for HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4-PRONG LUERS due to an increase in reports of alarms such as "Check Lines & Bags" and "Reload the Set 156" occurring during use of the HomeChoice cyclor which may prevent the HomeChoice system from initiating the therapy cycle.	HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4-PRONG LUERS	MDA/FCA/P1881-13129605-2026	GB79279741418	VANTIVE SDN BHD kai.xin.lim@vantive.com

21	30/07/2026	044 CN POC 26-008 Epoc Host2 & NXS Host Positive bias on creatinine and other parameters calculated using creatinine.	EPOC BLOOD ANALYSIS SYSTEM	MDA/FCA/P1885-76708942-2026	IVDC7557621-75750	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
22	31/07/2026	FA-001553- Beckman Coulter has determined that a software defect in AU480 Chemistry Analyzers using Microsoft® SQL Server 2022 Express may cause a DBConnectionError that renders AlarmDB unreadable and prevents instrument startup. The issue is associated with transaction log auto-growth, and may cause delays in reporting patient test results to physicians	AU 480 Analyzer	MDA/FCA/P1887-52922345-2026	IVDA6207123-155235	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.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.