



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING APRIL 2026

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	07/04/2026	VITROS™ Chemistry Products Mg Slides May Not Meet On-Analyzer Stability Specification	VITROS CHEMISTRY PRODUCTS ELECTROLYTES REAGENTS	MDA/FCA/P1733-55180019-2026	GD9627525-205666	T T MEDICAL MANAGEMENT SDN BHD ttcsdt05@gmail.com
2	09/04/2026	2024-PD-MR-016 Philips MR system breast coils Potential for harm while using a breast coil	MR 5300	MDA/FCA/P1735-97001639-2026	GC4777625-217427	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
3	14/04/2026	Field Safety Notification for Flexitron System - Intrauterine tube (IU tube)	FLEXITRON SYSTEM	MDA/FCA/P1736-94420885-2026	IVDC51660257518	NYPRAX BUSINESS SOLUTIONS kenna@nyprax.com
4	09/04/2026	FA1536 SynchroMed Flex Infusion Mode - A810 Clinician Programmer Application	SYNCHROMED II PROGRAMMABLE PUMP SYSTEM AND ACCESSORIES	MDA/FCA/P1737-84052626-2026	GB7982922-110702	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
5	13/04/2026	Field Safety Action on weak or absent staining associated with specific lots of Artisan Periodic Acid-Schiff Stain Kit (AR165), Artisan Alcian Blue/PAS Stain Kit (AR169), Artisan PAS Green Stain Kit (AR172), and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit (AR178)	DAKO_HISTOLOGY/CYT OLOGY_HISTOLOGY/CYT OLOGY REAGENTS_ARTISAN SPECIAL STAIN	MDA/FCA/P1745-47535127-2026	GC2975220-43026	BITA LIFESCIENCE SDN. BHD. kmhow@bitalifesc.com.my
6	13/04/2026	Voluntary Recall for InZone Detachment System due to Premature Battery Drainage	INZONE DETACHMENT SYSTEM	MDA/FCA/P1746-54168593-2026	GC84604193017	STRYKER CORPORATION (MALAYSIA) SDN. BHD. yenny.anggoro@stryker.com
7	13/04/2026	MR015/25/P (CAN) - Distribution of a Customer Advisory Notice to inform MR customers that Siemens	MAGNETOM PRISMA	MDA/FCA/P1747-97632639-2026	GC5206022-82422	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com

		Healthineers has incorporated a mandatory visual inspection and improved helium leak check of the venting system into the routine annual maintenance procedure, with clear intervention criteria for when to de ice the magnet via established service procedures				
8	17/04/2026	ETC Beadchip Kit Exposure Test Carrier Low Signal Results in BeadChip™ Assays	PRECISETYPE HEA MOLECULAR BEADCHIP TEST	MDA/FCA/P1749-41278792-2026	GC13082609918	BMS DIAGNOSTICS (M) SDN BHD rqa.my@biomedglobal.com
9	17/04/2026	Blood Pressure Monitor YE660E with the situation where the information of the Outdated Labelling, QR Code Discrepancy and Labelling / IFU Compliance	YUWELL ELECTRONIC BLOOD PRESSURE MONITOR	MDA/FCA/P1750-10997906-2026	GD17535444617	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
10	20/04/2026	da Vinci X, Xi Systems Cannula Mount Screws Breakage	DA VINCI XI SURGICAL SYSTEM, ENDOSCOPIC INSTRUMENT CONTROL SYSTEM, MODEL IS4000	MDA/FCA/P1751-61224737-2026	GB18651834218	DTG MEDICAL SDN BHD lifang.tan@devicetechnologies.asia
11	20/04/2026	Xpert Carba-R incorrect shipment to Malaysia	XPERT CARBA-R ASSAY	MDA/FCA/P1753-72098743-2026	GC82521235717	RADIOMETER MALAYSIA SDN. BHD. jngwei.chan@radiometer.my
12	22/04/2026	ABL800 - Cybersecurity vulnerabilities	ABL8XX SERIES BLOOD GAS ANALYZERS	MDA/FCA/P1757-22640254-2026	GC59959884718	RADIOMETER MALAYSIA SDN. BHD. jngwei.chan@radiometer.my
13	22/04/2026	ABL90 FLEX & ABL90 FLEX PLUS - Cybersecurity vulnerabilities	ABL90 FLEX	MDA/FCA/P1758-88425376-2026	GD958991229918	RADIOMETER MALAYSIA SDN. BHD. jngwei.chan@radiometer.my
14	27/04/2026	Potential failure of the mechanical ventilation – Extension of TSB13 (MDA/FCA/P1007-13171759-2024)	ATLAN	MDA/FCA/P1760-60719092-2026	GC4930621-68598	DRAEGER MALAYSIA SDN BHD afrina.ramli.contractor@draeger.com

15	28/04/2026	Olympus to Provide Update on Instruction for Use (IFU).	SINGLE LIGATION DEVICE_HX-400U-30	MDA/FCA/P1763-30087646-2026	GD69454346817	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
16	29/04/2026	2025-IGT-BST-020 - Philips Allura and Azurion systems Deaeration hose of tube cooling unit may degrade over time and develop oil leakage, potentially leading to loss of imaging functionality or exposure of users and/or patients to fumes	AZURION 3	MDA/FCA/P1764-43880030-2026	GC92659835718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
17	29/04/2026	2025-IGT-BST-020 - Philips Allura and Azurion systems Deaeration hose of tube cooling unit may degrade over time and develop oil leakage, potentially leading to loss of imaging functionality or exposure of users and/or patients to fumes	AZURION 7	MDA/FCA/P1766-75420104-2026	GC98026871418	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
18	29/04/2026	2025-IGT-BST-020 - Philips Allura and Azurion systems Deaeration hose of tube cooling unit may degrade over time and develop oil leakage, potentially leading to loss of imaging functionality or exposure of users and/or patients to fumes	AZURION BIPLANE	MDA/FCA/P1767-20693483-2026	GC91655727318	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
19	29/04/2026	2024-IGT-PUN-009 Zenition 10 Arcing in X-ray tube potentially leading to temporary loss of imaging functionality	ZENITION 10	MDA/FCA/P1768-95809475-2026	GB4127824-160695	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
20	30/04/2026	2024-IGT-BST-023 Philips Azurion Systems Mechanical wear of the Float Tabletop control potentially leading to limited availability or loss	AZURION 3	MDA/FCA/P1769-64198925-2026	IVDB7126524-184610	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com



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		of longitudinal and transverse table movements and/or lacerations				
21	30/04/2026	2024-IGT-BST-023 Philips Azurion Systems Mechanical wear of the Float Tabletop control potentially leading to limited availability or loss of longitudinal and transverse table movements and/or lacerations	AZURION 7	MDA/FCA/P1770-99059540-2026	IVDA9233125-201119	PHILIPS MALAYSIA SENDIRIAN BERHAD am.zarina@philips.com
22	30/04/2026	2024-IGT-BST-023 Philips Azurion Systems Mechanical wear of the Float Tabletop control potentially leading to limited availability or loss of longitudinal and transverse table movements and/or lacerations	AZURION BIPLANE	MDA/FCA/P1771-34505839-2026	IVDA9233125-201119	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.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.