



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING JULY 2025

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1.	05/07/2025	Hypromellose 0.3% W/V Eye Drops Without Preservative (AIN Opththal Mellose) With Safety and Performance Issue	HYPROMELLOSE 0.3% W/V EYE DROPS WITHOUT PRESERVATIVE	MDA/FCA/PX1311-19039480-2025	GB5836723-114988	AIN MEDICARE SDN BHD amirah@ainmedicare.com.my
2.	03/07/2025	ABL90 FLEX and ABL90 FLEX PLUS - Analyzer May Cease to Perform Calibrations Upon Restart	ABL90 FLEX	MDA/FCA/P1329-50752364-2025	IVDC5590952317	RADIOMETER MALAYSIA SDN. BHD ahila.padmanathan@radiometer.my
3.	08/07/2025	INNOVANCE VWF Ac - Elevated Control and Patient Sample Results	INNOVANCE VWF AC	MDA/FCA/P1334-87016889-2025	IVDC4353824-168298	SYSMEX (MALAYSIA) SDN. BHD. 603-56371788
4.	01/07/2025	Automated Impella Controller (Aic) Could Not Detect Pumps	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1335-89426102-2025	GD9474523-140294	DCH AURIGA (M) SDN BHD vibagarsukumaran@dchauriga.com
5.	02/07/2025	PFA_4010746 - Tourniquet Cuffs 5921-024-235, 5921-018-135, 5921-018-235 - Loss of Pressure - Detached Flange	STRYKER SMARTPUMP TOURNIQUE SYSTEM	MDA/FCA/P1337-62169875-2025	GB83002796818	STRYKER CORPORATION (MALAYSIA) SDN. BHD. joanne.fong@stryker.com
6.	03/07/2025	GE Healthcare – Certain MR Systems – Functional Check of MR Table Caster Locks During Planned Maintenance	OPTIMA MR450W 1.5T	MDA/FCA/P1338-29785669-2025	GB17854320917	GE HEALTHCARE SDN. BHD premarket.my@ge.com



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7.	03/07/2025	GE Healthcare – Certain MR Systems – Functional Check of MR Table Caster Locks During Planned Maintenance	SIGNA PREMIER	MDA/FCA/P1340-2 7664088-2025	GB4732721-52963	GE HEALTHCARE SDN. BHD premarket.my@ge.com
8.	04/07/2025	False Resistant Colistin (Cs02n) In VITEK® 2 AST GN Cards	VITEK® 2 AST-N439	MDA/FCA/P1343-6 4731909-2025	IVDB6843824-161221	BIOMERIEUX MALAYSIA SDN BHD michael.conlon@biomerieux.com
9.	04/07/2025	False Resistant Colistin (Cs02n) In VITEK® 2 AST GN Cards For Acinetobacter Baumannii Complex and Pseudomonas Aeruginosa	VITEK® 2 ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) CARD	MDA/FCA/P1345-8 1037322-2025	IVDB7784623-128365	BIOMERIEUX MALAYSIA SDN BHD michael.conlon@biomerieux.com
10.	07/07/2025	2024-PD-MR-023 Philips MR Systems Gradient Coil Component Failures May Act as A Heat Source with Potential to Produce Smoke and/or Fire.	INGENIA 1.5T, INGENIA 3.0T	MDA/FCA/P1346-5 7143498-2025	GB63162332517	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
11.	07/07/2025		INGENIA AMBITION	MDA/FCA/P1347-8 6178611-2025	GB2356219-30045	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
12.	07/07/2025		INGENIA ELITION	MDA/FCA/P1348-9 5281166-2025	GB179941251719	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
13.	07/07/2025	2024-PD-MR-023 Philips MR Systems Gradient Coil Component Failures May Act as a Heat Source with Potential to Produce Smoke and/or Fire.	MR 5300	MDA/FCA/P1349-9 9925107-2025	GB2458922-104130	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
14.	09/07/2025	FA-001384 UIBC OSR61205 Is Not Meeting Interference Claims for Haemoglobin Interference Serum Application.	ANAEMIA	MDA/FCA/P1350-7 1344575-2025	IVDB10309423-125411	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com



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15.	08/07/2025	FA-25050- BEC Identified an Issue on Unicel Dxi 800 Systems With Linear Slide PNP Gantries Running Software Versions 5.7 and Up.	UniCel Dxi Access Immunoassay Systems	MDA/FCA/P1350-6 3557838-2025	IVDA9233125-201119	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com
16.	09/07/2025	FA-25046-Multiple Customers Reported Receiving High Patient Results When Using Access Thyroglobulin Reagent Pack Lot 439163.	ANAEMIA	MDA/FCA/P1350-2 9954448-2025	IVDB10309423-125411	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com
17.	14/07/2025	(FCA2417) Air Dryer Drain Trap Nut Rust Prevention Measures Due to Different Parts	Automated Immunoassay System HISCL 5000 & HISCL 800	MDA/FCA/P1353-7 6669534-2025	IVDA6474623-114157	SYSMEX (MALAYSIA) SDN. BHD. cheah.kityin@sysmex.com.my
18.	09/07/2025	FA-25046-Multiple Customers Reported Receiving High Patient Results When Using Access Thyroglobulin Reagent Pack Lot 439163.	THYROID FUNCTION MARKERS	MDA/FCA/P1354-5 1221518-2025	IVDB7247723-115154	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com
19.	09/07/2025	035 FSCA POC 25-014 E poc BGEM BUN Test Card E poc Negative Sodium Bias on Multiple Test Card Lots	EPOC BLOOD ANALYSIS SYSTEM	MDA/FCA/P1356-5 2734074-2025	IVDC7557621-75750	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com

20.	14/07/2025	<p>PRODUCT NOTIFICATION: BDB-25-5314-FA BD FACS™ 7-Color Setup Beads BD Has Identified Errors in The Spectral Overlap Factors (SOF) Table Provided for Specific Lots of BD FACS™ 7-Color Setup Beads as Listed in The Table Above. This Issue May Affect the Accuracy of Flow Cytometry Data Due to Incorrect Flow Cytometry Setup Compensation Values for Multicolor Reagents for Which Proper Fluorescence Compensation Is Required Prior To Analyzing Samples</p>	<p>FLOW CYTOMETRY SYSTEM</p>	<p>MDA/FCA/P1357-6 6805320-2025</p>	<p>IVDA46167248618</p>	<p>BECTON DICKINSON SDN BHD RegAffairs_Mal@bd.com</p>
21.	14/07/2025	<p>(FCA2417) Air dryer drain trap nut rust prevention measures due to different parts</p>	<p>Sysmex_Automated Coagulation Analyzer_CN Series</p>	<p>MDA/FCA/P1358-7 7398188-2025</p>	<p>IVDC6362721-66356</p>	<p>SYSMEX (MALAYSIA) SDN. BHD. cheah.kityin@sysmex.com.my</p>
22.	17/07/2025	<p>Securement flange of Bivona® Aire-Cuf®, TTS™, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf®, TTS™, Cuffless FlexTend™, TTS™ FlexTend™ Adult Tracheostomy Tube(s) manufacturing defect</p>	<p>BIVONA SILICONE TRACHEOSTOMY TUBE</p>	<p>MDA/FCA/P1359-2 1123433-2025</p>	<p>GC8583224-187732</p>	<p>PRIMED MEDICAL SDN BHD primed_07@yahoo.com</p>
23.	24/07/2025	<p>Olympus to Provide Update on ESG-410 Board MoBiNE</p>	<p>ELECTROSURGICAL GENERATOR ESG-410</p>	<p>MDA/FCA/P1362-3 1457473-2025</p>	<p>GC5599621-63426</p>	<p>OLYMPUS (MALAYSIA) SDN. BHD. hideki.nagai@olympus.com</p>

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24.	24/07/2025	Shimadzu Radspeed Pro ceiling tube support - CH200/CH200M. Potential shaft failure on ceiling tube support may lead to support detachment, corrective measure required.	RADSPEED PRO	MDA/FCA/P1363-8 1813837-2025	GC4930621-68598	SHIMADZU MALAYSIA SDN BHD
25.	24/07/2025	97391810-FA RELIANCE ePTFE Gradual Rise in Shock Impedance Advisory Field Action	RELIANCE 4-FRONT LEADS AND ACCESSORIES	MDA/FCA/P1364-7 7833402-2025	GD6820621-78032	BOSTON SCIENTIFIC (MALAYSIA) SDN BHD charnhong.boey@bsci.com
26.	29/07/2025	97423085-FA Watchman Air Embolism	WATCHMAN™ TRUSEAL™ ACCESS SYSTEM	MDA/FCA/P1366-2 7626074-2025	GD8611519-30092	BOSTON SCIENTIFIC (MALAYSIA) SDN BHD charnhong.boey@bsci.com
27.	31/07/2025	Voluntary FSCA Fortress Introducer Sheath System - We have identified that some units within Lot Number 800989 of the Fortress Introducer System, 6F, Straight 45cm, may have been packaged with an incorrect pouch label.	FORTRESS INTRODUCER SHEATH SYSTEM, 5F AND 6F	MDA/FCA/P1367-3 1328093-2025	GB54392600818	BIOTRONIK MEDICAL DEVICES (MALAYSIA) SDN. BHD gary.yap@biotronik.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.