



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING OCTOBER 2025

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1.	01/10/2025	LOGIQ P9, P10 R4.5.7 Enhancement of UGAP Measurement Result LOGIQ P SERIES (LOGIQ P8, LOGIQ P9, LOGIQ P10) (GB4889221-73580)	LOGIQ P SERIES (LOGIQ P8, LOGIQ P9, LOGIQ P10)	MDA/FCA/P1424-54608372-2025	GB4889221-73580	GE HEALTHCARE SDN. BHD premarket.my@ge.com
2.	01/10/2025	LOGIQ P9, P10 R4.5.7 Enhancement of UGAP Measurement Result LOGIQ P SERIES (GB6568122-103525)	LOGIQ P SERIES	MDA/FCA/P1425-26916987-2025	GB6568122-103525	GE HEALTHCARE SDN. BHD premarket.my@ge.com
3.	07/10/2025	FA-25071- Beckman Coulter has confirmed a software anomaly on Dxl 9000 analyzers that may prevent correct application of user-specified manual dilution factors when ordering additional tests for samples already "In Progress" using the same "Sample ID number".	ACCESS PROGESTERONE II	MDA/FCA/P1427-80767855-2025	IVDB9522424-187370	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
4.	07/10/2025	FA-25071- Beckman Coulter has confirmed a software anomaly on DxC 500i analyzers that may prevent correct application of user-specified manual dilution factors when ordering additional tests for samples already "In Progress" using the same "Sample ID number".	DxC 500i AU Chemistry Module	MDA/FCA/P1428-64045206-2025	IVDA8913224-171351	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
5.	03/10/2025	2024-IGT-PUN-004 Zenition 50 Potential loss of imaging functionality and/or poor image quality	ZENITION 50	MDA/FCA/P1429-94718851-2025	GC2933619-31252	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com



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6.	07/10/2025	IDS-25-5176- EXP Product Cybersecurity Matter	BD PHOENIX™ AUTOMATED MICROBIOLOGY SYSTEM	MDA/FCA/P1433- 74532171-2025	IVDB10660623-151263	BECTON DICKINSON SDN BHD aqilah.lbrahim@bd.com
7.	14/10/2025	Olympus to Reinforce the IFU	SHOCKPULSE-SE LITHOTRIPSY SYSTEM	MDA/FCA/P1434- 67079874-2025	GC92154340917	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
8.	08/10/2025	FA-24068 - Supplier manufacturing nonconformance in PnP collet covers (C20585) from a Dec 2023-Jan 2024 batch causing overly thick flags to rub and damage Z-axis sensors (C20586).	UniCel Dxl Access Immunoassay Systems	MDA/FCA/P1435- 79338984-2025	IVDA9233125-201119	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
9.	09/10/2025	Potential mycobacterial contamination on Heater Unit HU35	HEATER UNIT HU35	MDA/FCA/P1436- 94754693-2025	GC6292720-45160	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
10.	13/10/2025	Olympus to Provide Online Training Materials on Reprocessing for TJF Duodenoscopes	EVIS EXERA III DUODENOVideoscope TJF-Q190V	MDA/FCA/P1437- 46822570-2025	GB4632321-70352	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
11.	15/10/2025	CentriMag Pump OOS not fitting in the CentriMag Motor	CENTRIMAG AND PEDIVAS EXTRACORPOREAL BLOOD PUMPING SYSTEM	MDA/FCA/P1438- 83908883-2025	GC37805334117	ABBOTT MEDICAL (MALAYSIA) SDN. BHD. RegulatoryMY@abbott.com
12.	15/10/2025	HeartMate Controller Backup Battery Fault	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	MDA/FCA/P1439- 69051125-2025	GD4151721-74880	ABBOTT MEDICAL (MALAYSIA) SDN. BHD. RegulatoryMY@abbott.com
13.	22/10/2025	AccuScreen DPOAE Probe - inducing technical distortions on high sound levels	MADSEN ACCUSCREEN	MDA/FCA/P1442- 90983973-2025	GB3401824-162662	ACCESS 2 HEALTHCARE SDN BHD eebin.liew@access2hc.com
14.	22/10/2025	Automated Impella Controller (AIC) Cybersecurity Notification	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1442- 88938875-2025	GD9474523-140294	DCH AURIGA (M) SDN BHD LimLiangJun@dchauriga.com



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15.	17/10/2025	PCS/MS – Potential FLEX-3S2P battery functional failures PORTRAIT VSM VITAL SIGNS MONITOR (GC7676824-159439)	PORTRAIT VSM VITAL SIGNS MONITOR	MDA/FCA/P1444-42806470-2025	GC7676824-159439	GE HEALTHCARE SDN. BHD premarket.my@ge.com
16.	17/10/2025	PCS/MS – Potential FLEX-3S2P battery functional failures CARESCAPE ONE (GC5319024-173964)	CARESCAPE ONE	MDA/FCA/P1445-24236001-2025	GC5319024-173964	GE HEALTHCARE SDN. BHD premarket.my@ge.com
17.	17/10/2025	PCS/MS – Potential FLEX-3S2P battery functional failures B105P/B105M/B125P/B125M/B155 M PATIENT MONITOR (GC5462723-144051)	B105P/B105M/B125P/B125M/B155M PATIENT MONITOR	MDA/FCA/P1446-71669218-2025	GC3218021-63208	GE HEALTHCARE SDN. BHD premarket.my@ge.com
18.	17/10/2025	PCS/MS – Potential FLEX-3S2P battery functional failures CARESCAPE MONITOR B450 (GC52869540718)	CARESCAPE MONITOR B450	MDA/FCA/P1447-66979970-2025	GC52869540718	GE HEALTHCARE SDN. BHD premarket.my@ge.com
19.	17/10/2025	PCS/MS – Potential FLEX-3S2P battery functional failures CARESCAPE B850 B650 B450 (GC7153322-104146)	CARESCAPE B850 B650 B450	MDA/FCA/P1448-54127603-2025	GC7153322-104146	GE HEALTHCARE SDN. BHD premarket.my@ge.com
20.	21/10/2025	FA-25054 Customer complaints were received for multiple Bicarbonate reagent lots associated with false high patient results for Bicarbonate. The high results are due to elevated levels of LDH in the patient samples tested. The current Bicarbonate product IFU’s do not advise of LDH interference with this assay.	BECKMAN COULTER ELECTROLYTE REAGENTS	MDA/FCA/P1450-60137067-2025	IVDB2268977017	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
21.	22/10/2025	Liquid leaking from the “Valve _Assy NO.339” built in CN	Sysmex_Automated Coagulation Analyzer_CN Series	MDA/FCA/P1451-18248256-2025	IVDC6362721-66356	SYSMEX (MALAYSIA) SDN. BHD Ho.Janice@sysmex.com.my

22.	22/10/2025	FA1524 CareLink Clinic Dashboard Display Correction	GUARDIAN CONNECT SYSTEM AND ACCESSORIES	MDA/FCA/P1453-95051837-2025	GB8317423-114689	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
23.	23/10/2025	Field Safety Notice on accuracy of Triglyceride, Total Cholesterol and Low-Density Lipoprotein Cholesterol analytes when using the Afinion™ Lipid Panel	AFINION LIPID PANEL	MDA/FCA/P1454-11351166-2025	IVDB74056332218	ABBOTT DIAGNOSTICS HEALTH SDN BHD winnielinlin.hii@abbott.com
24.	23/10/2025	003 FSCA AIMC 25-06 Follow Up Atellica IM ADVIA Centaur Homocysteine Calibrator Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability	ATELLICA® IM HOMOCYSTEINE (HCY)	MDA/FCA/P1455-79820434-2025	IVDB59216279518	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
25.	27/10/2025	2025-PD-CTAMI-107 - Philips CT Systems - Potential for System Shutdown and Expelled Parts	INCISIVE CT	MDA/FCA/P1462-60923675-2025	GC74519972618	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
26.	28/10/2025	Field action for InteliQ Immunology Control to revise the in-use stability claim for anti-cyclic Citrullinated Peptide (anti-CCP).	INTELIQ IMMUNOLOGY CONTROL	MDA/FCA/P1409-71638251-2025	IVDB9987521-63532	CHEMOPHARM SDN BHD gdpm@chemopharm.com
27.	29/10/2025	EA 9180 Na discrepant results	REFERENCE ELECTRODE	MDA/FCA/P1463-17401355-2025	IVDB7921024-186374	ROCHE DIAGNOSTICS (M) SDN. BHD wai_chin.koh@roche.com
28.	29/10/2025	A problem related to the device failing to start mechanical CPR after the software update to version 1.1.3 occurred	EASY PULSE - MECHANICAL CPR	MDA/FCA/P1467-69692714-2025	GC8466522-101961	SCHILLER ASIA PACIFIC SDN. BHD thiamhong.lim@schiller.com.my
29.	29/10/2025	Hoses of the Catheter Mounts may tear during use and lead to leakages (ErgoStars with smoothbore hoses).	DRAEGER SAVINA FAMILY	MDA/FCA/P1468-48690636-2025	GC84895244017	DRAEGER MALAYSIA SDN BHD afrina.ramli.contractor@draeger.com
30.	30/10/2025	Clear-Therm Mini Paediatric HMEF housings separate when a force is applied	BREATHING FILTERS, HMES AND HMEFS	MDA/FCA/P1469-95019061-2025	GB890231283619	INTERSURGICAL SDN BHD cheryl@intersurgical.com.my



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31.	30/10/2025	FA1511 Rev A_Potential for Suspension of Dynamic Sensing Algorithm Aurora EV-ICD (DVEA3E4)	AURORA EV-ICD™ SYSTEM	MDA/FCA/P1470-78365963-2025	GD2666524-159481	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
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* 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.