



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING AUGUST 2025

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1.	21/08/2025	Catheter Foley 2 Way Balloon with potential for water in the catheter balloon not being able to be removed and catheter balloon not being able to deflate	CATHETER FOLEY 2 WAY BALLOON	MDA/FCA/PX1229-80546460-2025	GB36726735318	MYMEDIC INNOVATION SDN BHD compliance@mymedic.com.my
2.	14/08/2025	Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP) System Over Temperature Field Action	CARDIOSAVE INTRA-AORTIC BALLOON PUMP	MDA/FCA/P1365-48897212-2025	GC2992923-137663	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
3.	07/08/2025	036 FSCA ACHC 24-07 2nd Follow Up Atellica CH Revised C Reactive Protein (RCRP) Incorrect Software Flagging for the Atellica CH Revised C Reactive Protein (RCRP) Assay	ATELLICA® CH REVISED C-REACTIVE PROTEIN (RCRP)	MDA/FCA/P1371-79785116-2025	IVDB10942623-142160	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
4.	07/08/2025	037 CN POC 25-015 Chek Stix Liquid QC Kit Foreign Material Identified in Quality Control Product	AUTOMATED URINE CHEMISTRY ANALYZER	MDA/FCA/P1372-62421682-2025	IVDB36827210418	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
5.	08/08/2025	Field Safety Notice Urgent Medical Device Correction – Potential for Loose Universal Surgical Manipulators on da Vinci X and Xi Systems (ISIFA2022-14-C)	DA VINCI XI SURGICAL SYSTEM, ENDOSCOPIC INSTRUMENT CONTROL SYSTEM, MODEL IS4000	MDA/FCA/P1373-37231744-2025	GC3810021-64842	DTG MEDICAL SDN BHD lifang.tan@devicetechnologies.asia

6.	11/08/2025	VITROS® Chemistry Products Ca Slides, Generations 67 and Above, May Experience Increased Incidence of Calibration Failures	VITROS CHEMISTRY PRODUCTS ELECTROLYTES REAGENTS	MDA/FCA/P1374-48492421-2025	IVDB7599223-142604	T T MEDICAL MANAGEMENT SDN BHD ar@ttmedical.com.my
7.	13/08/2025	MR040/25/S (CSAN), MR042/25/S - Inspection of Magnet Venting System	MAGNETOM SKYRA	MDA/FCA/P1377-24628432-2025	GB44064488717	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com
8.	13/08/2025	MR040/25/S (CSAN), MR042/25/S - Inspection of Magnet Venting System	MAGNETOM PRISMA	MDA/FCA/P1378-43240356-2025	GB75698797118	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
9.	13/08/2025	MR040/25/S (CSAN), MR042/25/S - Inspection of Magnet Venting System	MAGNETOM VIDA	MDA/FCA/P1378-65762248-2025	GB75575532218	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
10.	13/08/2025	MR040/25/S (CSAN), MR042/25/S - Inspection of Magnet Venting System	MAGNETOM LUMINA	MDA/FCA/P1378-91610863-2025	GB3902419-30683	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
11.	13/08/2025	FA-25056- on the DxC 500i Clinical Analyzer, when ordering a Clinical Chemistry (CC) combination test simultaneously with an Immunoassay (IA) test, if the IA test is processed between the CC constituent tests, the sample status of the CC test will remain "In Progress" with no error events.	DxC 500i AU Chemistry Module	MDA/FCA/P1382-16528305-2025	IVDA8913224-171351	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com

12.	14/08/2025	MR041/25/S (CSAN), MR042/25/S - Inspection of Magnet Venting System	MAGNETOM SPECTRA	MDA/FCA/P1383- 25259554-2025	GB64827212817	SIEMENS HEALTHCARE SDN. BHD yenli.lam@siemens- healthineers.com
13.	14/08/2025	038 FSCA ACHC 25-07 Atellica CH Urinary Cerebrospinal Fluid Protein (UCFP) Falsely Depressed Results for the Atellica CH UCFP Assay May Act as a Heat Source with Potential to Produce Smoke and/or Fire.	ATELLICA® CH URINARY/CEREBROSPIN AL FLUID PROTEIN (UCFP)	MDA/FCA/P1384- 50133025-2025	IVDB5927720-49887	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens- healthineers.com
14.	18/08/2025	The two housings of Various Clear- Therm Mini HMEF devices separate when a force is applied during handling	BREATHING FILTERS, HMES AND HMEFS	MDA/FCA/P1386- 20871349-2025	GB890231283619	INTERSURGICAL SDN BHD cheryl@intersurgical.com.my
15.	18/08/2025	Updating product-specific Instructions for Use (IFU) for Skull Traction Tong Large	AESULAP SURGICAL INSTRUMENT NEUROSURGERY	MDA/FCA/P1387- 98630904-2025	GD17535444617	B. BRAUN MEDICAL INDUSTRIES SDN. BHD. langfah.quek@bbraun.com
16.	18/08/2025	Urgent Medical Device Correction for the PrisMax Systems and TherMax Blood Warmer Units on PrisMax System alarm T2309, PrisMax System alarm T0830 and Thermax System may be unable to detect the presence of a bag on the Thermax Blood Warmer Unit leading to difficulty setting up therapy, or PrisMax System alarm T2284	PRISMAX	MDA/FCA/P1388- 32386631-2025	GC9127823-124035	VANTIVE SDN BHD kai.xin.lim@vantive.com



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17.	20/08/2025	NOTIFICATION ON POTENTIAL WEAK IMMUNOHISTOCHEMISTRY STAINING WITH FLEX Monoclonal Mouse Anti-Human CD20cy, Clone L26, Ready-to-Use (Dako Omnis), GA604	DAKO OMNIS (ATSI)-LYMPHATIC TISSUE AND BONE MARROW	MDA/FCA/P1390-13117620-2025	IVDC7441223-151113	BITA LIFESCIENCE SDN. BHD. kmhow@bitalifesc.com.my
18.	25/08/2025	FA-AM-FEB2025-305: Alinity M Software Update 1.9.0	ALINITY M SYSTEM	MDA/FCA/P1392-94280894-2025	IVDB7120020-41682	ABBOTT LABORATORIES (MALAYSIA) SDN. BHD. MDRA_Team_APAC@abbott.com
19.	25/08/2025	Urgent on replace of HU 35 Tank Fittings	HEATER UNIT HU35	MDA/FCA/P1393-95249345-2025	GC6292720-45160	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
20.	26/08/2025	039 FSCA ACHC 25-07 Follow Up Atellica CH Urinary Cerebrospinal Fluid Protein (UCFP) Potential for Falsely Depressed Results with the Atellica CH UCFP Assay	APELLICA® CH URINARY/CEREBROSPINAL FLUID PROTEIN (UCFP)	MDA/FCA/P1395-19923798-2025	IVDB5927720-49887	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.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.