

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	02/02/2026	Xpert® Carba-R Sample Reagent Vial with Incorrect Volume	XPRT CARBA-R ASSAY	MDA/FCA/P1640-40868003-2026	IVDC6457221-74902	RADIOMETER MALAYSIA SDN. BHD. ahila.padmanathan@radiometer.my
2	03/02/2026	(PHC26-01.A.OUS) Protein S Ac kit lot 03628 – Protein S Ac Reagent lot 562954 may be cloudy after reconstitution.	SIEMENS PROTEIN S AC	MDA/FCA/P1641-25745633-2026	IVDC4691624-166628	SYSMEX (MALAYSIA) SDN. BHD. cheah.kityin@sysmex.com.my
3	04/02/2026	Discontinuation use and repair of TU2000 TRYTABLE	MMT TRYTABLE TU2000	MDA/FCA/P1646-99461683-2026	GA2807724-178157	MEDI-LIFE (M) SDN. BHD. christine@medi-life.com.my
4	05/02/2026	FCA2525: TS-10: Lift Drop Incident during Rack Jam Clearance	XR-SERIES AUTOMATED HEMATOLOGY ANALYZER	MDA/FCA/P1647-89136998-2026	IVDB6506724-170755	SYSMEX (MALAYSIA) SDN. BHD. cheah.kityin@sysmex.com.my
5	05/02/2026	Olympus Emphasis on Strict Adherence to Instructions for Use (IFU)	EUS ULTRASONIC VIDEOSCOPE SYSTEM	MDA/FCA/P1648-63811962-2026	GB79514818718	OLYMPUS (MALAYSIA) SDN. BHD. hideki.nagai@olympus.com
6	05/02/2026	FA-001491- Beckman Coulter has determined that some DxC 700 AU and AU5800 Clinical Chemistry Analyzers may unexpectedly generate some errors due to Microsoft® SQL Server® 2022 Express issue. If this issue occurs the system may stop analyzing, and cause delays in reporting patient test results to physicians.	DxC 700 Analyzer	MDA/FCA/P1649-92028478-2026	IVDA5467424-161450	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com
7	05/02/2026	LIFECODES LSA Class I Stability Failure	LIFECODES SINGLE ANTIGEN KITS	MDA/FCA/P1650-78301862-2026	IVDC75845124518	BMS DIAGNOSTICS (M) SDN BHD rqa.my@biomedglobal.com

8	06/02/2026	Field Safety Notice - STA Liatest D-Di Plus. Stago has identified a positive bias in D-Dimer results across the analytical range for the affected lots.	STA® - LIATEST® D-DI PLUS	MDA/FCA/P1651-19481110-2026	IVDC5347522-90795	ALL EIGHTS (M) SDN BHD all8@alleights.com.my
9	06/02/2026	015 FSCA IMC 26-03 IMMULITE 2000 EPO and IMMULITE EPO Control Module EPO Adjustor and Control Module Open Vial Instability	IMMULITE 2000 EPO	MDA/FCA/P1653-60601548-2026	IVDB1287363017	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com
10	09/02/2026	CVG-21-Q3-21 Rev AC, HVAD Pump Failure to Restart Algorithm C	HEARTWARE™ VENTRICULAR ASSIST DEVICE (HVAD™) ACCESSORIES SYSTEM	MDA/FCA/P1654-58219598-2026	GD2555223-122718	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
11	10/02/2026	Olympus to Provide Impacted Customer With a Copy of the Instructions for Use (IFU)	CELONLAB ENT SYSTEM	MDA/FCA/P1659-81299459-2026	GC35106930618	OLYMPUS (MALAYSIA) SDN. BHD. hideki.nagai@olympus.com
12	11/02/2026	Important Security Notice for Centricity Universal Viewer Centricity Universal Viewer (GB5328025-213680)	CENTRICITY UNIVERSAL VIEWER	MDA/FCA/P1663-28353720-2026	GB5328025-213680	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
13	12/02/2026	GEM PREMIER 5000 BLOOD GAS SYSTEM Issue: Performance issue with specific GEM PAKs for the GEM Premier 5000 with iQM2 (Intelligent Quality Management) may experience an increased incidence of “Process Control Solution Not Detected” (PCSND) errors during warm-up, including consecutive occurrences, resulting in GEM PAK ejection and requiring a new GEM PAK insertion.	GEM PREMIER 5000 BLOOD GAS SYSTEM	MDA/FCA/P1664-90928076-2026	IVDC33500201118	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my

14	13/02/2026	Device Name: HEMOSIL REAGENTS - HemosIL Factor V Leiden Issue: Reduction in the on-board instrument stability claim for all current and future lots of HemosIL Factor V Leiden when used on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series hemostasis systems.	HEMOSIL REAGENTS	MDA/FCA/P1665-66157857-2026	IVDB75996368519	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
15	14/02/2026	FA1514 MiniMed Pump Placement with Respect to Infusion Site	MINIMED 700 INSULIN PUMP AND KIT	MDA/FCA/P1666-83333705-2026	GC8922821-64034	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
16	14/02/2026	FA1514 MiniMed Pump Placement with Respect to Infusion Site	MINIMED 780G SYSTEM AND ACCESSORIES	MDA/FCA/P1667-59518771-2026	GC4190021-62126	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
17	14/02/2026	FA1514 MiniMed Pump Placement with Respect to Infusion Site	PARADIGM VEO INSULIN PUMP	MDA/FCA/P1668-71818633-2026	GC8904122-88631	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
18	14/02/2026	FA1514 MiniMed Pump Placement with Respect to Infusion Site	MINIMED 640G SYSTEM AND ACCESSORIES	MDA/FCA/P1669-52527916-2026	GC8430922-106837	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
19	14/02/2026	FA1514 MiniMed Pump Placement with Respect to Infusion Site	THE MINIMED PARADIGM INSULIN PUMP	MDA/FCA/P1670-21003774-2026	GC8737122-88537	MEDTRONIC MALAYSIA SDN BHD cherie.ang@medtronic.com
20	19/02/2026	2026-CC-SRC-002: Trilogy Evo, Trilogy Evo O2, Trilogy EV300 Non-pneumatic Nebulizer Use, Flow Sensor Nebulized Aerosol Deposition, and Obstruction Alarm	TRILOGY EVO	MDA/FCA/P1673-56947816-2026	GC2627520-39891	PHILIPS MALAYSIA SENDIRIAN BERHAD shireenn.tiam@philips.com
21	19/02/2026	2026-CC-SRC-002: Trilogy Evo, Trilogy Evo O2, Trilogy EV300 Non-pneumatic Nebulizer Use, Flow Sensor Nebulized Aerosol Deposition, and Obstruction Alarm	TRILOGY EV300	MDA/FCA/P1675-32908560-2026	GC5498920-50666	PHILIPS MALAYSIA SENDIRIAN BERHAD shireenn.tiam@philips.com

22	20/02/2026	Field Safety Notification for Locking adapter/s to the Leksell Gamma Knife	LEKSELL GAMMA KNIFE (LGK)	MDA/FCA/P1680-43676500-2026	GC9257822-110526	NYPRAX BUSINESS SOLUTIONS kenna@nyprax.com
25	23/02/2026	Confirming Intended Reagent is Loaded During Manual Load Procedures	VITROS IMMUNODIAGNOSTIC PRODUCTS FERTILITY & PREGNANCY HORMONES & PROTEINS	MDA/FCA/P1681-84081900-2026	IVDB7258323-129195	T T MEDICAL MANAGEMENT SDN BHD ar@ttmedical.com.my
26	23/02/2026	VITROS™ Immunodiagnostic Products Progesterone 2 Calibrators – Potential for Calibration or Quality Control Failures	VITROS IMMUNODIAGNOSTIC PRODUCTS PROGESTERONE 2	MDA/FCA/P1682-14057287-2026	IVDB3167525-214895	T T MEDICAL MANAGEMENT SDN BHD ar@ttmedical.com.my
29	25/02/2026	ABL90 FLEX PLUS - Analyzer may abort capillary samples	ABL90 FLEX	MDA/FCA/P1687-55374265-2026	IVDC5590952317	RADIOMETER MALAYSIA SDN. BHD ahila.padmanathan@radiometer.my
30	26/02/2026	Device Name: HemosIL Factor XIII Antigen Issue: Reduction in the on-board instrument stability claim for all in-date and future lots of HemosIL Factor XIII Antigen (Part No. 0020201300) when used on the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series hemostasis systems.	HEMOSIL FACTOR XIII ANTIGEN	MDA/FCA/P1688-60639833-2026	IVDC2356823-153931	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
31	27/02/2026	017 FSCA AHC 26-04 Atellica CH Enzymatic Hemoglobin A1c (A1c_E) Potential for Depressed Results with Atellica CH Enzymatic Hemoglobin A1c when Processing Atellica CH	ATELLICA® CH ENZYMATIC HEMOGLOBIN A1C (A1C_E)	MDA/FCA/P1689-24384977-2026	IVDB9845619-35149	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING FEBRUARY 2026

		Revised C-Reactive Protein on the Same Analyzer				
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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.