



**MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING NOVEMBER 2025**

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1.	12/11/2025	Design update and user advice on specimen container device.	SPECIMEN CONTAINER	MDA/FCA/PX1452-45333494-2025	GA6143792916	MUZAMAL INDUSTRIES SDN BHD m.muza@muzamal.my
2.	04/11/2025	2025-PD-US-004 Philips Ultrasound Lumify Systems Lumify Systems incompatible with iOS 18 device)	LUMIFY ULTRASOUND SYSTEM	MDA/FCA/P1471-93352653-2025	GB11274413717	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
3.	04/11/2025	2024-IGT-PUN-011 Zenition 10 C-Arc Cable issue potentially leading to loss of imaging functionality	ZENITION 10	MDA/FCA/P1472-50179657-2025	GC3311823-138282	PHILIPS MALAYSIA SDN BERHAD joshua.chan@philips.com
4.	06/11/2025	Olympus to Reinforce the IFU & To Provide Supplemental Guidance	SINGLE LIGATION DEVICE_HX-400U-30	MDA/FCA/P1473-87877739-2025	GB467001260819	OLYMPUS (MALAYSIA) SDN. BHD. hideki.nagai@olympus.com
5.	06/11/2025	Olympus to Reinforce the Endoscope Reprocessors Operation Manual	ENDOSCOPE REPROCESSOR_OER-AW	MDA/FCA/P1475-69729658-2025	GC2422865416	OLYMPUS (MALAYSIA) SDN. BHD. hideki.nagai@olympus.com
6.	07/11/2025	005 CN ACHC 26-02 Atellica CH Triglycerides_2 (Trig_2)   Atellica CH Triglycerides_2 (Trig_2) Not Meeting Pack and Lot Calibration Interval	APELLICA® CH TRIGLYCERIDES_2 (TRIG_2)	MDA/FCA/P1478-12903351-2025	IVDB5423122-84212	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com
7.	14/11/2025	Kendall SCD™ 700 Sequential Compression System – Event-2025-07350 Kendall SCD™ 700 Sequential Compression System due to potential safety risks when used with non-Original Equipment Manufacturer (non-OEM) power cords.	KENDALL SCD COMPRESSION SYSTEM AND ACCESSORIES	MDA/FCA/P1479-15066503-2025	GB75980838218	INSAN DAMAI SDN BHD annton_chin@insandamai.com

8.	13/11/2025	006 CN ACHC 26-01 Atellica CH Gentamicin (Gent)   Atellica CH Gentamicin (Gent) Not Meeting Pack Calibration Interval on the Atellica CI Analyzer (C20585) from a Dec 2023-Jan 2024 batch causing overly thick flags to rub and damage Z-axis sensors (C20586).	A TELLICA® CH GENTAMICIN (GENT)	MDA/FCA/P1479-80952628-2025	IVDC38639183118	SIEMENS HEALTHCARE SDN. BHD. aili.siow@siemens-healthineers.com
9.	13/11/2025	IDS-25-5412 : BD BACTEC™ MGIT™ 960 PZA Kit	SUSCEPTIBILITY AND IDENTIFICATION TEST FOR MYCOBACTERIA	MDA/FCA/P1481-30172356-2025	IVDC23724200218	BECTON DICKINSON SDN BHD RegAffairs_Mal@bd.com
10.	14/11/2025	Technical alarms appearing randomly during use.	DEFIGARD TOUCH 7	MDA/FCA/P1483-37004177-2025	GC9551022-105940	SCHILLER ASIA PACIFIC SDN. BHD. thiamhong.lim@schiller.com.my
11.	17/11/2025	FA13NOV2025 Alinity ci-series Product Correction - Four (4) potential issues with the Alinity ci-series System software versions 3.6.1 and lower.	ALINITY I PROCESSING MODULE	MDA/FCA/P1484-63523044-2025	IVDA3247720-46201	ABBOTT LABORATORIES (MALAYSIA) SDN. BHD khenghoe.kwa@abbott.com.
12.	17/11/2025	Patient Medical History Data Persistence Failure in ViewPoint™ 6 versions 6.15.3 and 6.15.4 Ultrasound Software VIEWPOINT 6 (GB9473024-174386)	VIEWPOINT 6	MDA/FCA/P1488-10398662-2025	GB9473024-174386	GE HEALTHCARE SDN. BHD premarket.my@ge.com
13.	18/11/2025	FA-25054-B- FA-25054-B - Customer complaints were received for multiple Bicarbonate reagent lots associated with false high patient results for Bicarbonate	BECKMAN COULTER ELECTROLYTE REAGENTS	MDA/FCA/P1489-13321643-2025	IVDB2268977017	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com

14.	20/11/2025	FA-25078- Beckman Coulter has determined that Access 2 RVs lots listed above may contain manufacturing deformities. The bottom (round end) of the RV may have a small protrusion or hair like deformity.	Access 2 Immunoassay System	MDA/FCA/P1490-82400403-2025	IVDA9285425-200627	BECKMAN COULTER MALAYSIA SDN. BHD. song01@beckman.com
15.	25/11/2025	Incorrect X-Ray output when using dual X-Ray tube after serial radiography selection.	REMOTE-CONTROLLED R/F SYSTEM	MDA/FCA/P1493-46790281-2025	GC81874835818	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
16.	21/11/2025	Deviations of Elecsys® Anti-TSHR assay on cobas® e 411, cobas e 402 and cobas e 801 Device Name: Elecsys® Anti-TSHR assay	ROCHE DIAGNOSTICS GMBH_IMMUNOCHEMISTRY_THYROID FUNCTION MARKERS	MDA/FCA/P1496-95271116-2025	IVDB6682624-182011	ROCHE DIAGNOSTICS (M) SDN. BHD. chai_yin.heng@roche.com
17.	26/11/2025	Potential severe injury due to unintended disconnection of LAF1000 transfer tube from LLA210-S needle during or after brachytherapy treatment	HDR AFTERLOADER	MDA/FCA/P1500-39420278-2025	GC37143296817	ONCORAY SDN BHD vincent@oncoray.com.my
18.	27/11/2025	Unexpected shutdown of Carestation 600 and 700 Series Anesthesia Systems, containing certain power management boards, when AC mains power is disconnected or AC mains power is lost CARESTATION 650 A1, CARESTATION 650C A1, CARESTATION 620 A1 (GC5901122-104148)	CARESTATION 650 A1, CARESTATION 650C A1, CARESTATION 620 A1	MDA/FCA/P1505-23546721-2025	GC5901122-104148	GE HEALTHCARE SDN. BHD premarket.my@ge.com



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19.	27/11/2025	Unexpected shutdown of Carestation 600 and 700 Series Anesthesia Systems, containing certain power management boards, when AC mains power is disconnected or AC mains power is lost CARESTATION 700 SERIES (GC2333221-51495)	CARESTATION 700 SERIES	MDA/FCA/P1506-36576644-2025	GC2333221-51495	GE HEALTHCARE SDN. BHD premarket.my@ge.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.