MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING DECEMBER 2025

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	12/12/2025	KERR ENDODONTICS K-FILES HAND FILES - Field Safety Notice to correct IFU for cleaning time and typos	KERR ENDODONTICS K-FILES HAND FILES	MDA/FCA/P1485-66161130-2025	GA2877324-180637	EHC COMMERCIAL MALAYSIA SDN. BHD. RAQASEA@envistaco.com
2	12/12/2025	KERR ENDODONTICS HEDSTROM HAND FILES - Field Safety Notice to correct IFU for cleaning time and typos	KERR ENDODONTICS HEDSTROM HAND FILES	MDA/FCA/P1486-42193501-2025	GC81874835818	EHC COMMERCIAL MALAYSIA SDN. BHD. RAQASEA@envistaco.com
3	09/12/2025	A potential issue was identified where the electromagnetic contactors are welded in the cabinet of the X-ray high-voltage generator, due to age degradation may cause continuous current flow even after shutdown, leading to possible overheating and device damage; a field corrective action will be implemented to prevent this.	REMOTE-CONTROLLED R/F SYSTEM	MDA/FCA/P1491-18920993-2025	GD9627525-205666	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
4	01/12/2025	Intracranial Pressure Monitor Pressio 2 Monitor Reboot Issue Due to Catheter Memory Corruption	PRESSIO INTRACRANIAL PRESSURE AND TEMPERATURE MONITORING SYSTEM	MDA/FCA/P1504-99314995-2025	GC4777625-217427	I.MEDIC PLT cl_lim2001@yahoo.com
5	01/12/2025	Unexpected shutdown of Carestation 700 Series Anesthesia Systems, containing certain power management boards, when AC mains power is disconnected or AC mains power is lost CARESTATION 700 SERIES (GC4777625-217427)	CARESTATION 700 SERIES	MDA/FCA/P1507-18659597-2025	IVDC51660257518	GE HEALTHCARE SDN. BHD premarket.my@ge.com

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING DECEMBER 2025

6	02/12/2025	Xpert® CT/NG assays false negative due to escape mutants	XPERT CT/NG	MDA/FCA/P1510-65368455-2025	GB7982922-110702	RADIOMETER MALAYSIA SDN. BHD. jngwei.chan@radiometer.my
7	02/12/2025	Laerdal Compact Suction Unit 4, RTCA (LCSU 4 – RTCA) Version emitting beyond the acceptable limits for RTCA application specified in RTCA DO-160G Chapter 21, Equipment Category M	LAERDAL COMPACT SUCTION UNIT 4 (LCSU 4)	MDA/FCA/P1511-45392626-2025	IVDC74609321918	LAERDAL MALAYSIA SDN BHD Angie.Goh@laerdal.com
8	05/12/2025	Xpert® BCR-ABL Ultra False Under Quantitation	XPERT BCR-ABL ULTRA	MDA/FCA/P1512-82035188-2025	GC2975220-43026	RADIOMETER MALAYSIA SDN. BHD. jngwei.chan@radiometer.my
9	03/12/2025	2025-CC-HPM-033 - IntelliVue Patient Monitor MX850, MX750, Active Display AD85 and Active Display AD75 - Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms	INTELLIVUE PATIENT MONITOR MX750 & MX850	MDA/FCA/P1513-89698755-2025	GC84604193017	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
10	03/12/2025	2025-CC-HPM-033 - IntelliVue Patient Monitor MX400, MX450, MX500, MX550 & IntelliVue MMX - Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms	INTELLIVUE PATIENT MONITOR MX400-550 SERIES	MDA/FCA/P1514-30083507-2025	GC5206022-82422	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
11	03/12/2025	2025-CC-HPM-033 - IntelliVue Patient Monitor MX100 & IntelliVue Multi-Measurement Module X3 - Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms	INTELLIVUE MX100 AND X3	MDA/FCA/P1515-87710769-2025	GC13082609918	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING DECEMBER 2025

12	04/12/2025	2025-CC-HPM-033 - INTELLIVUE MP5 - Potential for delayed treatment or adverse events when switching off Patient Monitor Alarms	INTELLIVUE MP5, MP5T & MP5SC PATIENT MONITOR	MDA/FCA/P1516-89822650-2025	GD17535444617	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
13	16/12/2025	Safety Information to inform customers about the correct handling and use of the MINOP® TROCAR - FF399R.	AESCULAP SURGICAL INSTRUMENT NEUROSURGERY	MDA/FCA/P1518-42904626-2025	GB18651834218	B. BRAUN MEDICAL INDUSTRIES SDN. BHD. langfah.quek@bbraun.com
14	05/12/2025	2025-EI-RI-004 - Vue PACS (Diagnostic) and Vue Motion version 12.2.8.600 - Potential for misdiagnosis due to Bookmark not preserving the original measurement specified by the user upon subsequent access following version 12.2.8.600 upgrade.	PHILIPS VUE PACS	MDA/FCA/P1519-89119626-2025	GC82521235717	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
15	09/12/2025	2025-IGT-BST-013 Philips Azurion R3.0 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications	AZURION 7	MDA/FCA/P1520-84395290-2025	GC59959884718	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
16	09/12/2025	2025-IGT-BST-013 Philips Azurion R3.0 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications	AZURION BIPLANE	MDA/FCA/P1521-67496360-2025	GD958991229918	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com

17	09/12/2025	Advice on Instructions for Use of BK Medical Ultrasound system type 1300 with Battery Option	BK1300 BKSPECTO ULTRASOUND SCANNER SYSTEMS	MDA/FCA/P1523-17673542-2025	GC4930621-68598	MEDI-LIFE (M) SDN. BHD. pamela.lim@medi-life.com.my
18	09/12/2025	A potential issue was identified where the electromagnetic contactors are welded in the cabinet of the X-ray high-voltage generator, due to age degradation may cause continuous current flow even after shutdown, leading to possible overheating and device damage; a field corrective action will be implemented to prevent this.	RADSPEED PRO	MDA/FCA/P1524-48647908-2025	GD69454346817	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
19	09/12/2025	Advice on Instructions for Use of BK Medical Ultrasound system type 2300 with Battery Option	BK MEDICAL BK2300 ULTRASOUND SCANNER SYSTEM	MDA/FCA/P1525-50078774-2025	GC92659835718	MEDI-LIFE (M) SDN. BHD. pamela.lim@medi-life.com.my
20	09/12/2025	A potential issue was identified where the electromagnetic contactors are welded in the cabinet of the X-ray high-voltage generator, due to age degradation may cause continuous current flow even after shutdown, leading to possible overheating and device damage; a field corrective action will be implemented to prevent this.	X-RAY TV SYSTEM	MDA/FCA/P1526-76000419-2025	GC98026871418	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
21	09/12/2025	A potential issue was identified where the electromagnetic contactors are welded in the cabinet of the X-ray high-voltage generator, due to age degradation may cause continuous current flow even after shutdown, leading to possible	DIGITAL ANGIOGRAPHY SYSTEM	MDA/FCA/P1527-47417781-2025	GC91655727318	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my

		overheating and device damage; a field corrective action will be implemented to prevent this.				
22	09/12/2025	A potential issue was identified where the electromagnetic contactors are welded in the cabinet of the X-ray high-voltage generator, due to age degradation may cause continuous current flow even after shutdown, leading to possible overheating and device damage; a field corrective action will be implemented to prevent this.	RADIOGRAPHY SYSTEM	MDA/FCA/P1528-23421382-2025	GB4127824-160695	SHIMADZU MALAYSIA SDN BHD cwyeong@shimadzu.com.my
23	12/12/2025	Mazor X™ robotic guidance system Model TPL0059, Software Version 5.0.1 or 5.1.2 or 5.1.3 System Software update to version 5.2	MAZOR X SYSTEM AND ACCESSORIES	MDA/FCA/P1529-54496298-2025	IVDB7126524-184610	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
24	15/12/2025	Automated Digital Cell Morphology Analyzer DI-60 Barcode reader issue	AUTOMATED DIGITAL CELL MORPHOLOGY ANALYZER DI-60	MDA/FCA/P1530-19528793-2025	IVDA9233125-201119	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
25	15/12/2025	FA-25079- DxI 600/800 instruments running Windows 10 unexpectedly transition to "Pause/Not Ready" mode due to wash buffer flow monitoring issues, cancelling in-progress tests. This requires users to manually initialize, prime, and reload affected tests, disrupting workflow and diagnostic output	UniCel DxI Access Immunoassay Systems	MDA/FCA/P1531-54697935-2025	IVDA9233125-201119	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
26	15/12/2025	FA-25059- Beckman Coulter UniCel DxI 600 and 800 instruments fail to start after rebooting because the AuObj.exe software does not launch.	UniCel DxI Access Immunoassay Systems	MDA/FCA/P1532-93836101-2025		BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com

		A specific LED pattern on MCC cards confirms a hardware startup fault. This nonconformance requires FSE intervention.				
27	15/12/2025	HISCL Anti-TP False Negative Result	HISCL Anti-TP False Negative Result	MDA/FCA/P1533-91490848-2025	IVDC57839114818	SYSMEX (MALAYSIA) SDN. BHD.
28	15/12/2025	HISCL Anti-TP False Negative Result	HISCL ANTI-TP ASSAY KIT	MDA/FCA/P1534-34157712-2025	IVDD5667724117	SYSMEX (MALAYSIA) SDN. BHD Ho.Janice@sysmex.com.my
29	15/12/2025	Replacement with Improved Version of HISCL Anti-HBc Assay Kit	HISCL ANTI-HBC ASSAY KIT	MDA/FCA/P1535-56083440-2025	IVDC6362721-66356	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
30	15/12/2025	CN series - Sample arm B pipette damage issue	Sysmex_Automated Coagulation Analyzer_CN Series	MDA/FCA/P1536-56663091-2025	IVDA5543624-159885	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
31	16/12/2025	cobas c 703 Reaction Cell Wash Units Premature Tubing failure	Cobas Pro integrated solutions	MDA/FCA/P1537-92722464-2025	GC82521235717	ROCHE DIAGNOSTICS (M) SDN. BHD.
32	16/12/2025	2025-IGT-BST-012 Philips Azurion R2.1.10 and 2.2.10 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications	AZURION 7	MDA/FCA/P1538-47328027-2025	GC10785320-48186	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
33	16/12/2025	2025-IGT-BST-012 Philips Azurion R2.1.10 and 2.2.10 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result	AZURION 5	MDA/FCA/P1539-12673142-2025	GC99381544218	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com

		in a delay or termination of procedure and/or procedural complications				
34	16/12/2025	2025-IGT-BST-012 Philips Azurion R2.1.10 and 2.2.10 Systems Potential loss of imaging (X-ray) functionality, and/or loss of motorized movement, and/or incorrect image content, and/or loss of data which may result in a delay or termination of procedure and/or procedural complications	AZURION 3	MDA/FCA/P1541-40421252-2025	GC43835501717	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.com
35	18/12/2025	Olympus to Reinforce the Warnings in the IFU	ELECTROSURGICAL KNIFES	MDA/FCA/P1542-50225377-2025	IVDB10942623-142160	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
36	17/12/2025	011 FSCA ACHC 24-07 3rd Follow Up Atellica CH Revised C Reactive Protein (RCRP) | Resolution of the Incorrect Software Flagging for the Atellica CH Revised C Reactive Protein (RCRP) Assay on the Atellica CI Analyzer	ATELLICA® CH REVISED C-REACTIVE PROTEIN (RCRP)	MDA/FCA/P1543-22790351-2025	GC92154340917	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
37	19/12/2025	Olympus to Provide Supplemental Guidance	SHOCKPULSE-SE LITHOTRIPSY SYSTEM	MDA/FCA/P1546-53023405-2025	IVDB10943324-173555	OLYMPUS (MALAYSIA) SDN. BHD. mes-ra.oml@olympus.com
38	22/12/2025	EliA™ ANA Positive Control 250 & EliA™ ANA Positive Control 200: Update to EliA La Acceptance Range Information	ELIA METHOD SPECIFIC REAGENTS MARKER	MDA/FCA/P1548-41074400-2025	GC15931545518	BIOMARKETING SERVICES (M) SDN BHD rqa.my@biomedglobal.com
39	29/12/2025	2025-CC-EC-018 - Efficia DFM100 Defibrillator/Monitor (866199) - Boot-Up Failure with SW 2.00.33	EFFICIA DFM100 DEFIBRILLATOR	MDA/FCA/P1554-21208907-2025	GA2116024-179663	PHILIPS MALAYSIA SDN BERHAD zam.zarina@philips.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.