

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	04/05/2026	HIGH LEVEL DISINFECTANT 5L WITH 0.15% PERACETIC ACID WITH ISSUE OF EXCESSIVE ODOUR, BUBBLE, CORROSION AND DISCOLORATION	HIGH LEVEL DISINFECTANT PERACETIC ACID	MDA/FCA/PX1732-90447526-2026	GC7485024-157847	MYMEDIC INNOVATION SDN BHD farkhan@mymedic.com.my
2	05/05/2026	2025-IGT-BST-005 Philips Azurion Potential loss of imaging functionality (Allura/Azurion)	AZURION 3	MDA/FCA/P1772-82223106-2026	GC99381544218	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
3	05/05/2026	2025-IGT-BST-005 Philips Azurion Potential loss of imaging functionality (Allura/Azurion)	AZURION 7	MDA/FCA/P1773-16560561-2026	GC82521235717	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
4	05/05/2026	2025-IGT-BST-005 Philips Azurion Potential loss of imaging functionality (Allura/Azurion)	AZURION BIPLANE	MDA/FCA/P1774-93003376-2026	GC59959884718	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
5	05/05/2026	FSCA – Genexus Dx Software Cybersecurity Vulnerability	Genexus™ Dx Integrated Sequencer	MDA/FCA/P1776-98445959-2026	IVDA7155723-146952	BIOMARKETING SERVICES (M) SDN BHD regulatory.my@biomedglobal.com
6	06/05/2026	Windows license activation of Internet connection from Sysmex Analyzer	AUTOMATED HEMATOLOGY ANALYZER XN SERIES	MDA/FCA/P1779-71069583-2026	IVDB4650226-222618	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
7	08/05/2026	030 FSCA AIMC 25-06 2nd Follow Up Atellica IM and ADVIA Centaur Homocysteine Calibrator Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability	ATELLICA® IM HOMOCYSTEINE (HCY)	MDA/FCA/P1782-75693614-2026	IVDB59216279518	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
8	12/05/2026	User Manual Update for TU2000 TRYTABLE	MMT TRYTABLE TU2000	MDA/FCA/P1789-92320142-2026	GA2807724-178157	MEDI-LIFE (M) SDN. BHD. pamela.lim@medi-life.com.my

9	12/05/2026	Merlin Programmer Pacing Capture Test in Aveir Leadless Pacer	MERLIN PATIENT CARE SYSTEM & PACING SYSTEM ANALYZER	MDA/FCA/P1790-92552622-2026	GC9743622-98481	ABBOTT MEDICAL (MALAYSIA) SDN. BHD. RegulatoryMY@abbott.com
10	12/05/2026	031 CN AHC 24-06 Follow Up Atellica CH Lactate_3 Resolution of Atellica CH Lactate_3 (Lac_3) Onboard Reagent Instability	ATELLICA® CH LACTATE_3 (LAC_3)	MDA/FCA/P1792-82303684-2026	IVDB5904622-106142	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
11	14/05/2026	IntelliCuff (Standalone) – Cuff System Leakage and Continuous Pumping Issue	HAMILTON-INTELLICUFF	MDA/FCA/P1795-48362407-2026	GC561911093218	STAR MEDIK SDN BHD starmedik@gmail.com
12	14/05/2026	CASETM v7– Thermal Printer Assembly [CASE CARDIAC TESTING SYSTEM	CASE CARDIAC TESTING SYSTEM	MDA/FCA/P1798-12235854-2026	GB64876396017	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
13	14/05/2026	ApexPro CARESCAPE Telemetry Server v5.0 and v6.0 with CARESCAPE Central Station or CIC Pro Clinical Information Center	APEXPRO TELEMETRY SYSTEM	MDA/FCA/P1799-35789378-2026	GC96351485517	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
14	15/05/2026	032 CN AIMC 24-03 Follow Up Atellica IM Rubella IgG (Rub G) and ADVIA Centaur Rubella G Resolution: Potential for Invalid Calibrations with Atellica IM and ADVIA Centaur Systems Rubella IgG Assay	ATELLICA® IM RUBELLA IGG (RUB G)	MDA/FCA/P1800-49316367-2026	IVDC17674265918	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
15	20/05/2026	Field Safety Corrective Action (FSCA) / Voluntary Medical Device Recall (Correction) for Automated Impella Controller (AIC) and Impella Optical Controller – Potential Software Error Causing Unexpected System Restart and Temporary Pump Stop	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1802-62492946-2026	GD9474523-140294	DCH AURIGA (M) SDN BHD LimLiangJun@dchauriga.com



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING MAY 2026

16	20/05/2026	AX018/26/S (FSCA) & AX019/26/S (CSI) - SW Update VE40B Patch5	ARTIS ICONO FAMILY	MDA/FCA/P1803-64531942-2026	GC7669520-43102	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
17	21/05/2026	O-arm™ O2 Imaging System Detector Panel Firmware Update (Identifier: BI-700-02000) (FA1542)	O-ARM O2 IMAGING SYSTEM AND ACCESSORIES	MDA/FCA/P1804-70792708-2026	GC10794122-104946	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
18	26/05/2026	To advise discrepancies between the Operation Manual and the device screen prompts, to enhance the information for the users - Terumo Recording & Automatic Blood Collector	TERUMO RECORDING & AUTOMATIC BLOOD COLLECTOR	MDA/FCA/P1805-55587640-2026	GA12928200617	TERUMO MALAYSIA SDN. BHD. TMSB_RAQ@terumo.co.jp

* 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.