

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING AUGUST 2026

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1	06/08/2026	Electric Shock Incident happened to user when using registered medical device (Hydrafacial Elite-GB3699926-223705)	HYDRAFACIAL MD ELITE	MDA/FCA/P1884-34969787-2026	GB3699926-223705	NEOASIA (M) SDN BHD kahmun.goh@neoasiagroup.com
2	02/08/2026	Phase II Auto Suture™ Trocar - Updated IFU Availability	AUTOSUTURE BLUNT TIP TROCAR	MDA/FCA/P1888-21138378-2026	GB72185514917	MEDTRONIC MALAYSIA SDN BHD dl.myreg@medtronic.com
3	04/08/2026	2026-CC-HPM-008 - Philips IntelliVue Patient Monitors Continuous Reboot with Active Display	PHILIPS INTELLIVUE INFORMATION CENTER IX APPLICATION SW	MDA/FCA/P1892-56788314-2026	GC56105716618	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
4	06/08/2026	A review of Na ⁺ results from normal patient populations on the GEM Premier 5000 and GEM Premier 7000 systems shows a negative bias relative to the published serum reference range. To optimize alignment with this reference range, Werfen will implement an adjustment to the Na ⁺ setting in future PAK lots. This adjustment applies a shift of approximately +3 mM across the Na ⁺ analytical measurement range.	GEM PREMIER 5000 BLOOD GAS SYSTEM	MDA/FCA/P1895-34617485-2026	IVDC33500201118	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
5	13/08/2026	Carescape™ Central Station (CSCS) V3.0.x A software issue may delay patient monitoring for at least 3 minutes after a system restart, potentially delaying detection of significant patient events.	CARESCAPE CENTRAL STATION	MDA/FCA/P1896-53319695-2026	GC6222122-94374	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING AUGUST 2026

		CARESCAPE CENTRAL STATION (GC6222122-94374)				
6	13/08/2026	Aisys CS2, Aisys CS2 with Et Control and S/5 Aisys Anesthesia Systems automatically transitioning to Alternate O2 control AISYS CS2 (GC59982267817)	AISYS CS2	MDA/FCA/P1899-43325425-2026	GC59982267817	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
7	17/08/2026		CENTRICITY PACS (RA1000)	MDA/FCA/P1900-46275901-2026	GB9159425-211220	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
8	18/08/2026	Field Safety Corrective Action (FSCA) / Voluntary Medical Device Correction (Notification) for Automated Impella Controller (AIC) - Correction of the purge pressure sensor assembly within the AIC.	IMPELLA CP® WITH SMARTASSIST® SET	MDA/FCA/P1902-72638487-2026	GD9474523-140294	DCH AURIGA (M) SDN BHD LimLiangJun@dchauriga.com
9	17/08/2026	Potential for Incorrect Patient and Study Association Following Historical Data Migration from a Legacy System to Enterprise Archive with Core Services Hub/ Workflow Core Services or to Centricity PACS or to standalone Enterprise Archive Centricity Enterprise Archive (GA8749724-164527)	CENTRICITY ENTERPRISE ARCHIVE	MDA/FCA/P1904-44519949-2026	GA8749724-164527	GE HEALTHCARE SDN. BHD premarket.my@gehealthcare.com
10	17/08/2026	APM-26-06129 ForeSightTM Oximeter Cable Labels Switched (Affected model number: HEMFSM10)	HEMOSPHERE ADVANCED MONITORING PLATFORM	MDA/FCA/P1905-94635971-2026	GC766371236819	EDWARDS LIFESCIENCES (MALAYSIA) SDN BHD WaiYi_Wong@edwards.com

MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING AUGUST 2026

11	17/08/2026	APM-26-06129 ForeSight™ Oximeter Cable Labels Switched (Affected model number: HEMFSM10)	HEMOSPHERE ALTA ADVANCED MONITORING PLATFORM	MDA/FCA/P1906-73625075-2026	GC8808625-209005	EDWARDS LIFESCIENCES (MALAYSIA) SDN BHD WaiYi_Wong@edwards.com
12	18/08/2026	FA-26031- Beckman Coulter received customer complaints of lamina fluid leaks in iQ200 Series and DxU 840m/850m Analyzers.	IQ200 SERIES URINE MICROSCOPY SYSTEM (INTERNATIONAL)	MDA/FCA/P1907-58227455-2026	IVDB5900924-166640	BECKMAN COULTER MALAYSIA SDN. BHD. nbintiabdaziz@beckman.com
13	19/08/2026	045 FSCA ACHC 26-10 Atellica CH Revised C-Reactive Protein (RCRP) Potential for Falsely Elevated or Flagged Results When Using the Atellica CH Revised C-Reactive Protein (RCRP) Assay	ATELLICA® CH REVISED C REACTIVE PROTEIN (RCRP)	MDA/FCA/P1908-48458196-2026	IVDB10942623-142160	SIEMENS HEALTHCARE SDN. BHD. yenli.lam@siemens-healthineers.com
14	24/08/2026		FILMARRAY PNEUMONIA PANEL PLUS	MDA/FCA/P1909-47394229-2026	IVDC3485124-165919	BIOMERIEUX MALAYSIA SDN BHD ruhil.ashvinkumar@biomerieux.com
15	24/08/2026	MEDICAL DEVICE CORRECTION Hemospray Endoscopic Hemostat	HEMOSTASIS DEVICES	MDA/FCA/P1910-67514500-2026	GB8677723-144784	COOK ASIA (MALAYSIA) SDN BHD RA-Malaysia@CookMedical.com
16	27/08/2026	2026-PD-CTAMI-003 Spectral CT with software version V5.0, V5.2, or V5.4 Image artifacts, wrong slice thickness, unintended motion	SPECTRAL CT	MDA/FCA/P1911-65549958-2026	GC6307722-96412	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com
17	27/08/2026		DRAEGER HEATED BREATHING CIRCUIT	MDA/FCA/P1912-94257962-2026	GB10569223-152691	DRAEGER MALAYSIA SDN BHD afrina.ramli.contractor@draeger.com
18	27/08/2026	2026-CC-HPM-010 - Philips IntelliVue Patient Monitors Continuous Reboot with Active Display	INTELLIVUE PATIENT MONITOR MX750 & MX850	MDA/FCA/P1913-29885875-2026	GC2975220-43026	PHILIPS MALAYSIA SENDIRIAN BERHAD zam.zarina@philips.com



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING AUGUST 2026

19	28/08/2026		D-100 HEMOGLOBIN TESTING SYSTEM	MDA/FCA/P1914-18941550-2026	IVDB4821967817	CHEMOPHARM SDN BHD gdpmd@chemopharm.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.