



MEDICAL DEVICE FIELD CORRECTIVE ACTION LISTING SEPTEMBER 2025

No.	Date Received	Title of FCA	Affected Medical Device	MDA Reference Number	MDA Registration Number	Local Establishment Contact Detail
1.	03/09/2025	ROTEM® sigma ROTROL P Issue: Werfen has identified that the ROTEM sigma ROTROL P lot 32400122, has a higher than expected likelihood of generating quality control out of range results in INTEM C CT or HEPTEM C CT assays in conjunction with cartridge lots numbers between S240101 and S250209.	ROTE M® SIGMA	MDA/FCA/P1391-72488197-2025	IVDC10235825-198676	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
2.	11/09/2025	Unexpected shutdown of the Cardiosave IABP	CARDIOSAVE INTRA-AORTIC BALLOON PUMP	MDA/FCA/P1396-59869486-2025	GC2992923-137663	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
3.	09/09/2025	Olympus to Provide Updates to the Instruction for Use (IFU) for Olympus Bronchofiberscope, Bronchovideoscope.	EVIS EXERA III BRONCHOVIDEOSCOPE SYSTEM	MDA/FCA/P1400-77640407-2025	GB58878308917	OLYMPUS (MALAYSIA) SDN. BHD mes-ra.oml@olympus.com
4.	05/09/2025	Field Safety Notice (FSN) relating to the stability of the Oxazepam analyte contained in Multi-Drug Calibrator / Control products	URINE ENZYME IMMUNOASSAY	MDA/FCA/P1401-27639706-2025	IVDB10629319-34166	ABBOTT DIAGNOSTICS HEALTH SDN BHD winnielinlin.hii@abbott.com
5.	10/09/2025	DEFIGARD HD-7 - intermittent contact with removable adult defibrillation paddles (IM00967)	DEFIGARD HD-7	MDA/FCA/P1403-42710881-2025	GC10563625-202352	SCHILLER ASIA PACIFIC SDN. BHD. thiamhong.lim@schiller.com.my

6.	10/09/2025	MAC™ VU360 RESTING ECG ANALYSIS SYSTEM MAC VU360 Acquisition Module Holder	MAC™ VU360 RESTING ECG ANALYSIS SYSTEM	MDA/FCA/P1404-90746410-2025	GB4693721-52965	GE HEALTHCARE SDN. BHD premarket.my@ge.com
7.	10/09/2025	Failure modes of Heartstring Seal	HEARTSTRING III PROXIMAL SEAL SYSTEM	MDA/FCA/P1405-89405336-2025	GB7745523-127193	RBD HEALTHCARE SDN BHD sookpei@rbdhealthcare.com
8.	19/09/2025	Field action for InteliQ Immunology Control to revise the in-use stability claim for anti-cyclic Citrullinated Peptide (anti-CCP).	INTELIQ IMMUNOLOGY CONTROL	MDA/FCA/P1409-71638251-2025	IVDB9987521-63532	CHEMOPHARM SDN BHD gdpmd@chemopharm.com
9.	18/09/2025	PLT-I value, low recovery and high variability	SYSMEX_HAEMATOLOGY_OTHER HAEMATOLOGY TESTS	MDA/FCA/P1410-85562302-2025	IVDB17531114618	SYSMEX (MALAYSIA) SDN. BHD. Ho.Janice@sysmex.com.my
10.	18/09/2025	Lower calcium recovery in Level 3 of Liquid Unassayed Multiqual.	LIQUID UNASSAYED MULTIQUAL CONTROL	MDA/FCA/P1411-86923514-2025	IVDB6550720-49432	CHEMOPHARM SDN BHD gdpmd@chemopharm.com
11.	18/09/2025	Lower calcium recovery in Level 3 of InteliQ Assayed Multiqual Control	INTELIQ ASSAYED MULTIQUAL CONTROL	MDA/FCA/P1412-94150682-2025	IVDC6673524-164751	CHEMOPHARM SDN BHD gdpmd@chemopharm.com
12.	18/09/2025	Lower calcium recovery in InteliQ Assayed Multiqual Control	INTELIQ ASSAYED MULTIQUAL CONTROL	MDA/FCA/P1413-43736204-2025	IVDC6673524-164751	CHEMOPHARM SDN BHD gdpmd@chemopharm.com

13.	19/09/2025	FA18SEP2025 Alinity hq Analyzer software versions 5.0 to 5.10.1 does not visibly apply appropriate flag IG and NEU results when saturation is present, which may prevent users from recognizing potentially impacted values.	ALINITY HQ ANALYZER	MDA/FCA/P1415-68416906-2025	IVDB31515121518	ABBOTT LABORATORIES (MALAYSIA) SDN. BHD. MDRA_Team_APAC@abbott.com
14.	19/09/2025	Lower calcium recovery in InteliQ Assayed Multiqual Control.	LIQUICHEK ASSAYED CHEMISTRY CONTROL	MDA/FCA/P1416-64076949-2025	IVDB2758923-133131	CHEMOPHARM SDN BHD gdpm�@chemopharm.com
15.	22/09/2025	Lyphocheck Assayed Chemistry Control – The reconstituted and refrigerated storage stability claim for Bilirubin (Direct) has been reduced to 4 days.	LYPHOCHEK® ASSAYED CHEMISTRY CONTROL	MDA/FCA/P1418-52051875-2025	IVDC97925103018	CHEMOPHARM SDN BHD gdpm�@chemopharm.com
16.	25/09/2025	Increased trend of complaint of probes unexpectedly failing to actuate and cut during use	CONSTELLATION VISION SYSTEM	MDA/FCA/P1419-63978441-2025	GC96073327017	ALCON LABORATORIES (M) SDN. BHD. ee_peng.yap@alcon.com
17.	26/09/2025	AW SERVER 3.2 Unauthorized access to the Service Tools Web Interface	AW SERVER 3.2	MDA/FCA/P1421-76846159-2025	GB3800423-134964	GE HEALTHCARE SDN. BHD premarket.my@ge.com
18.	30/09/2025	URGENT: MEDICAL DEVICE CUSTOMER NOTICE CADDTM Medication Cassette Reservoirs	CADD SOLIS AMBULATORY INFUSION PUMP	MDA/FCA/P1422-28559604-2025	GC5586521-80774	PRIMED MEDICAL SDN BHD primed_07@yahoo.com



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19.	30/09/2025	Device name: HemosIL Quality Controls Discontinuation of Reconstituted Stability Claims at 2-8°C.	HEMOSIL CONTROL ASSAYED	MDA/FCA/P1423-23386954-2025	IVDC87652271518	STRAITS SCIENTIFIC (M) SDN BHD straits@3s.com.my
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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.