

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2025**

Item	Manufacturer	link
Jan-25		
AquaFlexFlow UF 500 Plus extracorporeal blood circuits	Nuwellis	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-extracorporeal-blood-circuit-issue-nuwellis?utm_medium=email&utm_source=govdelivery
Fluid Delivery Sets	Medline	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-fluid-delivery-set-issue-medline?utm_medium=email&utm_source=govdelivery
Figulla Flex II ASD	Occlutech	https://ansm.sante.fr/informations-de-securite/dm-docclusion-intra-cardiaque-figulla-flex-ii-asd-occluder-occlutech-gmbh
Solution Sets	Baxter Healthcare Corporation	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-solution-set-issue-baxter-healthcare-corporation?utm_medium=email&utm_source=govdelivery
Cannulae - EOPA Arterial Cannula - Select Series Angled Tip Arterial Cannula	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/234
AXIOS Stent and Electrocautery Enhanced Delivery System	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishDetails/235
Dialysis machines.	Fresenius Medical Care.	https://ade.sfda.gov.sa/Fsca/PublishDetails/228
Eclipse Mini Eclipse PRO	Spacelabs Healthcare Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/232
Oxylog 3000 plus	Draeger Medical Systems Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/226

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2025**

PrisMax Systems	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/233
draft guidance: Pulse Oximeters for Medical Purposes	FDA	https://www.fda.gov/news-events/press-announcements/fda-proposes-updated-recommendations-help-improve-performance-pulse-oximeters-across-skin-tones?utm_medium=email&utm_source=govdelivery
Medrad Centargo CT Injection System	Imaxeon Pty Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/238
draft guidance: Pulse Oximeters for Medical Purposes	U.S. Food and Drug Administration	https://www.fda.gov/news-events/press-announcements/fda-proposes-updated-recommendations-help-improve-performance-pulse-oximeters-across-skin-tones?utm_medium=email&utm_source=govdelivery
VasoView HemoPro 2 (VH-4000 and VH-4001) Endoscopic Vessel Harvesting Systems	Getinge	https://www.fda.gov/medical-devices/medical-device-recalls/endoscopic-vessel-harvesting-evh-system-correction-getinge-and-maquet-cardiovascular-update-use?utm_medium=email&utm_source=govdelivery
	U.S. Food and Drug Administration (FDA)	https://www.fda.gov/medical-devices/medical-devices-news-and-events/medical-device-supply-chain-vulnerabilities-and-public-health-impact-they-have-our-most-vulnerable?utm_medium=email&utm_source=govdelivery
	U.S. Food and Drug Administration (FDA)	https://www.fda.gov/medical-devices/letters-health-care-providers/update-evaluation-airborne-chemicals-neonatal-incubators-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
Ivenix Infusion System	Fresenius Kabi USA	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-infusion-pump-software-issue-fresenius-kabi-usa?utm_medium=email&utm_source=govdelivery
3M™ Prevena™ Plus 125 Therapy Units and Kits and 3M™ V.A.C.® Via Therapy Units and Kits distributed	KCI USA Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/249
Disposable insufflation needle	LANDANGER SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/244
Multiple products	Coloplast	https://ade.sfda.gov.sa/Fsca/PublishDetails/245

**MEDICAL DEVICES
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ROTEM® sigma complete. ROTEM® sigma complete + hep.	Werfen..	https://ade.sfda.gov.sa/Fsca/PublishDetails/250
VINYL EXAMINATION GLOVES	Anhui Intco Medical Products Co., Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/246
AD7 and AD7X patient tables which are part of Philips Allura and Azurion systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/265
Cardinal Health Presource Kits:	Cardinal Health 200, LLC..	https://ade.sfda.gov.sa/Fsca/PublishDetails/261
Medima Infusion Pump	ICU Medical, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/256
Medima P100, P200, and P300 Volumetric infusion Pumps	ICU Medical, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/255
Multiva 1.5T	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/262
Optipac Bone Cement	Zimmer Biomet	https://ade.sfda.gov.sa/Fsca/PublishDetails/254
Philips Allura and Azurion systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/263
Software update for the intensive care ventilator elisa 300/500/600/800/800VIT	Lowenstein Medical GmbH &Co.KG	https://ade.sfda.gov.sa/Fsca/PublishDetails/266
Zenition 50 and Zenition 70 systems	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/123

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2025**

Feb-25

StatStrip Glucose and Glucose/Ketone	Nova Biomedica	https://www.fda.gov/medical-devices/medical-device-recalls/glucose-and-glucoseketone-meter-correction-nova-biomedical-corporation-issues-software-correction?utm_medium=email&utm_source=govdelivery
Neo-Tee T-Piece Resuscitator	Mercury Medical	https://www.fda.gov/medical-devices/medical-device-recalls/gas-powered-emergency-resuscitator-recall-mercury-medical-removes-neo-tee-t-piece-resuscitator-due?utm_medium=email&utm_source=govdelivery
Alinity s System	Abbott GmbH. and Co. KG	https://ade.sfda.gov.sa/Fsca/PublishDetails/269
CARTO® OCTARAY™ Mapping Catheter with TRUEref™ Technology	Biosense Webster Inc. Jo	https://ade.sfda.gov.sa/Fsca/PublishDetails/272
GLUCOSE liquicolor	HUMAN Gesellschaft für Biochemica und Diagnostica	https://ade.sfda.gov.sa/Fsca/PublishDetails/267
Heater-Cooler Unit HCU 40	MAQUET Cardiopulmonary GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/271
Becker and Exacta EDMS	Medtronic Neurosurgery	https://www.fda.gov/medical-devices/medical-device-recalls/pressure-monitoring-device-recall-medtronic-neurosurgery-issues-correction-becker-and-exacta?utm_medium=email&utm_source=govdelivery
Life2000 Ventilator System	Baxter Healthcare	https://www.fda.gov/medical-devices/medical-device-recalls/continuous-ventilator-correction-baxter-healthcare-corporation-issues-correction-life2000-ventilator?utm_medium=email&utm_source=govdelivery
oxygen concentrators.	JIANGSU JUMAO X-CARE MEDICAL EQUIPMENT CO LTD	https://www.fda.gov/medical-devices/medical-device-recalls/oxygen-concentrator-recall-jiangsu-jumao-x-care-medical-equipment-co-ltd-removes-jmc5a-nitruaire-5?utm_medium=email&utm_source=govdelivery
diabetes devices	FDA Alert	https://www.fda.gov/medical-devices/safety-communications/fda-alerts-patients-regularly-check-diabetes-related-smartphone-device-alert-settings-especially?utm_medium=email&utm_source=govdelivery

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Rotarex Atherectomy Systems	Vascular, a subsidiary of Becton, Dickinson and Company (BD)	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-atherectomy-catheter-system-issue-bard-peripheral-vascular?utm_medium=email&utm_source=govdelivery
Integrated Arterial Catheters	Medline Industries, LP	https://www.fda.gov/medical-devices/medical-device-recalls/arterial-catheter-recall-medline-industries-lp-removes-integrated-arterial-catheters-due-excess?utm_medium=email&utm_source=govdelivery
Phasitron breathing circuit kits	Sentec/Percussionaire	https://www.fda.gov/medical-devices/medical-device-recalls/breathing-circuit-kit-recall-sentecpercussionaire-removes-vdr4-phasitron-breathing-circuits-due?utm_medium=email&utm_source=govdelivery
LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators	LivaNova PLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/277
TBS iNsight	medimaps group SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/279
Impella RP	Abiomed Inc	https://www.fda.gov/medical-devices/medical-device-recalls/heart-pump-recall-abiomed-inc-updates-use-instructions-impella-rp-smartassist-and-impella-rp-flex?utm_medium=email&utm_source=govdelivery
AlinIQ AMS	Abbott	https://ade.sfda.gov.sa/Fsca/PublishDetails/290
Aortic Root Cannula	Medtronic SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/285
Haemostatic Forceps	Aesculap	https://ade.sfda.gov.sa/Fsca/PublishDetails/287
MiniMed™ Paradigm™, MiniMed™ 600 series, and MiniMed™ 700 series insulin pump systems	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/286
Olympus MAJ-891 Forceps/Irrigation Plug (Isolated Type)	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/288