MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2025
Follow up for implants (by projects /programs department MOH)
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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

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Oxylog 3000 plus	Draeger Medical Systems Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/226
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draft guidance: Pulse Oximeters for Medical Purposes	FDA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draft guidance: Pulse Oximeters for Medical Purposes	U.S. Food and Drug Administration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

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Disposable insufflation needle	LANDANGER SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/244
Multiple products	Coloplast	https://ade.sfda.gov.sa/Fsca/PublishDetails/245
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

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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
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

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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
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

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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

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SpeedControl Dial component (not implant)	Max Mobility/Permobil	https://www.fda.gov/medical-devices/medical-device-recalls/power-assist-device-recall-max-mobilitypermobil-removes-speedcontrol-dial-component-used-smartdrive?utm_medium=email&utm_source=govdelivery
Allura and Azurion interventional fluoroscopy systems (not implant)	PhilIps	https://www.fda.gov/medical-devices/medical-device-recalls/patient-table-correction-philips-updates-use-instructions-allura-and-azurion-systems-due-patient?utm_medium=email&utm_source=govdelivery
Varipulse ablation catheter	Biosense Webster	https://www.fda.gov/medical-devices/medical-device-recalls/ablation-catheter-correction-biosense-webster-updates-use-instructions-varipulse-due-high-rate?utm_medium=email&utm_source=govdelivery
Regard newborn kits (not implant)	ROi CPS, LLC	https://www.fda.gov/medical-devices/medical-device-recalls/regard-newborn-kit-recall-roi-cps-llc-removes-certain-newborn-kits-due-recalled-component-neo-tee-t?utm_medium=email&utm_source=govdelivery

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Single Use Guide Sheath Kits (not implant)	Olympus	https://www.fda.gov/medical-devices/medical-device-recalls/endoscope-instrument-recall-olympus-removes-single-use-guide-sheath-kits-due-risk-radiopaque-guide?utm_medium=email&utm_source=govdelivery
MEDRAD Intego 200 PET Infusion Systems (not implant)	Bayer Healthcare LLC..	https://ade.sfda.gov.sa/Fsca/PublishDetails/300
CO2 Filter Line	Covidien LLC….	https://ade.sfda.gov.sa/Fsca/PublishDetails/301
Aisys CS2 ...anesthesia devices (not implant)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/62
ASSURITY™ AND ENDURITY™ PACEMAKERS	Abbott..	https://ade.sfda.gov.sa/Fsca/PublishDetails/302
HAMILTON-C2/C3	HAMILTON MEDICAL AG	https://ade.sfda.gov.sa/Fsca/PublishDetails/303
Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/305
Silvercel Hydro Alginate, (not implant)	Advanced Medical Solutions Limited..	https://ade.sfda.gov.sa/Fsca/PublishDetails/295
VARIPULSE™	Biosense Webster, Inc	https://ansm.sante.fr/informations-de-securite/dispositif-dablation-par-electroporation-rythmologie-catheter-varipulse-biosense-webster
fantômes de cols inclinés 8-M.	Keri Medical	https://ansm.sante.fr/informations-de-securite/orthopedie-fantome-de-col-incline-8-m-keri-medical

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s adaptateurs pourvoies respiratoires(not implant)	Smiths Medical	https://ansm.sante.fr/informations-de-securite/ventilateur-accessoire-adaptateurs-pour-voies-respiratoires-bci-smiths-medical
Vaporizer Sevoflurane(not implant)	Getinge	https://www.fda.gov/medical-devices/medical-device-recalls/vaporizer-recall-getinge-removes-vaporizer-sevoflurane-quick-fil-and-expands-recall-vaporizer?utm_medium=email&utm_source=govdelivery
Tack Endovascular Systems	Philips	https://www.fda.gov/medical-devices/medical-device-recalls/endovascular-system-recall-philips-removes-and-discontinues-distribution-tack-endovascular-system?utm_medium=email&utm_source=govdelivery
Canule de trachéotomie flexible Shiley™	Medtronic	https://ansm.sante.fr/informations-de-securite/canule-de-tracheotomie-flexible-shiley-pour-adultes-avec-chemise-interne-reutilisable-a-ballonnet-taperguard-covidien-llc-medtronic
Spectrum infusion pumps (not implant)	Baxter Healthcare Corporation	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-infusion-pump-issue-baxter-healthcare-corporation?utm_medium=email&utm_source=govdelivery
Delivery cable Flex-Pusher II (51FP100) in combination with Delivery system	Occlutech International AB	https://ade.sfda.gov.sa/Fsca/PublishDetails/310
ProPort™ Plastic Implantable Ports	Smiths Medical ASD, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/306
générateur thermiqueHCU 40	Maquet Cardiopulmonary GmbH	https://ansm.sante.fr/informations-de-securite/generateur-thermique-de-cec-heater-cooler-unit-hcu-40-maquet-cardiopulmonary-gmbh-getinge
valves anti-retour « Vaccum Relief Check Valve »	Livanova	https://ansm.sante.fr/informations-de-securite/cec-ecmo-consommable-circuit-set-vacuum-relief-check-valve-livanova
SynchroMed	Medtronic	https://ansm.sante.fr/informations-de-securite/pompe-implantable-accessoires-telecommande-patient-myptm-medtronic-inc

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BiPAP …..(not implant)	Philips Respironics	https://ansm.sante.fr/informations-de-securite/appareils-de-ventilation-bipap-a30-bipap-a30-efl-bipap-a30-hybrid-bipap-a40-bipap-a40-efl-bipap-a40-pro-philips-respironics
ProPort Plastic	Smiths Medical	https://www.fda.gov/medical-devices/medical-device-recalls/implantable-port-recall-smiths-medical-removes-proport-plastic-implantable-ports-due-manufacturing?utm_medium=email&utm_source=govdelivery
CVAC Aspiration Systems	Calyxo	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-aspiration-system-issue-calyxo?utm_medium=email&utm_source=govdelivery
BD Alaris Systems (not implant)	Becton, Dickinson	https://www.fda.gov/medical-devices/medical-device-recalls/infusion-pump-software-correction-becton-dickinson-and-company-bd-issues-correction-bd-alaris?utm_medium=email&utm_source=govdelivery
Rocket Thoracentesis Catheter 6Fg & 8Fg	Rocket Medical	https://ade.sfda.gov.sa/Fsca/PublishDetails/324
TruSystem 7500 Surgical Table Systems(not implant)	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/322
Vasoview Hemopro 2 (w/Vasoshield) Endoscopic Vessel Harvesting System(not implant)	MAQUET Cardiopulmonary GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/313
ORAL/NASAL Endotracheal Tubes	Smiths Medical	https://www.fda.gov/medical-devices/medical-device-recalls/endotracheal-tube-recall-smiths-medical-removes-intubation-oralnasal-endotracheal-tubes-due-smaller?utm_medium=email&utm_source=govdelivery
Aortic Root Cannulas	Medtronic	https://www.fda.gov/medical-devices/medical-device-recalls/vascular-cannula-recall-medtronic-removes-aortic-root-cannula-due-unexpected-loose-material-male?utm_medium=email&utm_source=govdelivery
Origin Data Management software versions 3.1.0, 3.1.1, 3.1.2, 3.2.0, 3.2.1	Brainlab AG	https://ade.sfda.gov.sa/Fsca/PublishDetails/329

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(CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems (collectively CHA)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/327
Carestation 620/650/650c and 750/750c Anesthesia Systems	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/328
25-نيسان		
Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/148
MR systems with 60cm wide bore	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/337
ZOLL Powerheart® G5 AED Product Family(it is notimplant)	Cardiac Science Corporation	https://ade.sfda.gov.sa/Fsca/PublishDetails/346
4008 S V10 hemodialysis machine(it is notimplant)	Fresenius Medical Care.	https://ade.sfda.gov.sa/Fsca/PublishDetails/341
072 Aspiration System “Hippo” (NON IMPLANT)	Q’Apel Medical, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/343
Philips CT Big Bore(it is notimplant)	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/344
CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line(it is	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/347

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IntelliSpace Cardiovascular(it is notimplant)	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/348
PowerPICC Intravascular Catheters	Bard Access Systems	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-intravascular-picc-catheter-issue-bd?utm_medium=email&utm_source=govdelivery
Centricity High Acuity Critical Care (CHA CC)(not implant)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/358
Ascenda™ Intrathecal Catheter	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/354
HeartMate Mobile Power Unit (MPU)	Abbott	https://www.fda.gov/medical-devices/medical-device-recalls/heart-pump-accessory-removal-abbott-removes-heartmate-mobile-power-unit-due-instances-sudden-power?utm_medium=email&utm_source=govdelivery
Cuffs and Two-Piece Reusable Blood Pressure Cuffs kits(its not implant)	Welch Allyn, Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/368
ParaPAC plus™ Model 300 and Model 310 Ventilator(not implant)	Smiths Medical ASD, Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/361
HKH 8820 Wall Holder(not implant)	MAQUET Cardiovascular LLC.	https://ade.sfda.gov.sa/Fsca/PublishDetails/371
FREEGO ENTERAL FEEDING PUMP(not implant)	Zevex International Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/39
MR systems with 60cm wide bore(its not implant)	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/337

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- Tec 6 Plus - Tec 820 ISO - Tec 820 SEV - Tec 850 ISO - Tec 850 SEV(its not implant)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/205