

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Item	Manufacturer	link
Jan-24		
KNEE SCORPION	Arthrex	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19668
Spaceplus Infusomat	B Braun	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19669
Infusomat Space	B Braun	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19670
Over-ear headphones	Siemens Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19671
Amplatz Steerable Delivery Sheath	Abbott	https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-amplatz-steerable-delivery-sheath-increased-risk-air-embolism?utm_medium=email&utm_source=govdelivery
Impella Left Sided Blood Pumps	Abiomed	https://www.fda.gov/medical-devices/medical-device-recalls/abiomed-recalls-all-impella-left-sided-blood-pumps-risk-motor-damage-after-contact-transcatheter?utm_medium=email&utm_source=govdelivery
TruSignal sensors	GE HealthCare	https://www.fda.gov/medical-devices/medical-device-recalls/ge-healthcare-recalls-trusignal-spo2-sensors-issues-may-reduce-defibrillation-energy-expose-patients?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B	Getinge Disinfection AB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19636
Proclaim™ XR SCS and Proclaim™ Elite SCS System, Proclaim™ DRG Neurostimulation System, Infinity™ DBS System	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19637
Cobalt XT, Cobalt, Crome ICDs and CRT-Ds	Medtronic	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy?utm_medium=email&utm_source=govdelivery
Claria MRI, Amplia MRI, Compia MRI, Viva, Brava CRT-Ds	Medtronic	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy?utm_medium=email&utm_source=govdelivery
Visia AF, Visia AF MRI, Evera, Evera MRI, Primo MRI, Mirro MRI ICDs	Medtronic	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-implantable-cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy?utm_medium=email&utm_source=govdelivery
NOxBOXi Nitric Oxide Delivery Systems	NOxBOX Ltd.	https://www.fda.gov/medical-devices/medical-device-recalls/noxbox-ltd-recalls-noxboxi-nitric-oxide-system-manifold-failure-may-cause-gas-leaks-and-interrupt?utm_medium=email&utm_source=govdelivery
Oxylog 3000 Plus	Draeger Medical	https://www.fda.gov/medical-devices/medical-device-recalls/draeger-medical-recalls-oxylog-3000-plus-emergency-and-transport-ventilators-risk-unexpected?utm_medium=email&utm_source=govdelivery
Alcon Phaco Tips	Alcon Laboratories Inc...	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19620

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

PowerSpiral PSF-1 and associated accessories DPST-1 and PSCU	Olympus	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19624
Atrium Advanta V12 Covered Stent System	Atrium Medical Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=19625
Zimmer® Periarticular Locking Plate System, Distal Lateral Femoral Plate – Right - 6 Holes – 159 mm Length	Zimmer Biomet.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19627
Allen Advance Chest Support with pad	Baxter Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19590
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19592
Dr.Disinfectant Instrument Transport Gel	Saudi Mais for Medical Products	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=15&rid=19594
HF-Resection Electrode	Olympus	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19600
VERITAS Advanced Infusion and Fluidics Packs	Johnson & Johnson Surgical Vision, Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=19602

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Durepair Dura Regeneration Matrix	Medtronic SA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19603
Full Vision Treadmill –(T2100-ST)	Full Vision Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19604
NO-Therapy device NO-A (in combination with ventilator Leoni Plus)	EKU Elektronik GmbH.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19572
Alinity ci-series System Control Module (SCM)	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19577
Oxylog 3000 plus	Draeger Medical Systems Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19578
Accu-Chek Solo diabetes manager	Roche Diabetes Care GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19580
The Timeter Sure Grip Flowmeter	Allied Healthcare Products Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=15&rid=19583
Ingenia Elition, SmartPath to Ingenia Elition X, MR 7700 and 'Upgrade to MR 7700' MR systems	Philips Healthcare.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19585

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

TruSignal SpO2 Sensors	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19586
MEGADYNE™ MEGA SOFT™ and MEGA 2000 Reusable Patient Return Electrodes	Megadyne Medical Products Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19587
da Vinci Xi/X Tip-Up Fenestrated Grasper	Intuitive Surgical Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19588
Impella 5.5 with SmartAssist	Abiomed	https://www.fda.gov/medical-devices/medical-device-recalls/abiomed-recalls-specific-impella-55-smartassist-purge-fluid-leaks-can-cause-pump-stop-and-loss?utm_medium=email&utm_source=govdelivery
Quadrox Oxygenators and certain Getinge/Maquet Venous Hardshell Cardiotomy Reservoirs	Getinge/Maquet	https://www.fda.gov/medical-devices/letters-health-care-providers/oxygenator-devices-used-extracorporeal-circulation-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
surgical N95 respirators and masks	O&M Halyard	https://www.fda.gov/medical-devices/safety-communications/update-recommendations-certain-om-halyard-surgical-n95-respirators-surgical-masks-and-pediatric-face?utm_medium=email&utm_source=govdelivery
Plum 360 Infusion System	ICU Medical, Inc	apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2023-RN-00607-1
Olympus Flexible Endoscopes	Olympus Medical Systems Corp.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19729

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

TruWave Disposable Pressure Transducer, FloTrac Sensors, Acumen IQ Sensors	Edwards Lifesciences	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19730
SoClean2 and SoClean3	SoClean	https://www.fda.gov/medical-devices/safety-communications/voluntary-recall-soclean-equipment-intended-use-cpap-devices-and-accessories-fda-safety?utm_medium=email&utm_source=govdelivery
VariSoft Infusion Sets	Unomedical A/S	https://www.fda.gov/medical-devices/medical-device-recalls/unomedical-recalls-varisoft-infusion-sets-due-damage-connector-piece-causing-unexpected?utm_medium=email&utm_source=govdelivery
Guardian™ 4 Sensor	Medtronic MiniMed	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19797
High Flow Insufflation Unit	Olympus Medical Systems Corp.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19801
Trilogy Evo and Trilogy Evo O2 Ventilators	Respironics, Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19802
XenMatrix™ Surgical Graft	Becton Dickinson & Co. (BD)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=15&rid=19804
TJF-Q190V/Q290V/Q170V DUODENOSCOPE	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19806

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

SynchroMed™ II	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19807
McGRATH™ MAC	Covidien LLC	https://www.fda.gov/medical-devices/medical-device-recalls/covidien-llc-recalls-mcgrath-mac-video-laryngoscope-due-stolen-defective-products?utm_medium=email&utm_source=govdelivery
Cardinal Health Monoject	Cardinal Health	https://www.fda.gov/medical-devices/medical-device-recalls/cardinal-health-recalls-monoject-disposable-syringes-incompatibilities-syringe-pumps?utm_medium=email&utm_source=govdelivery
Novum IQ Syringe Pump	Baxter Healthcare Corporation	https://www.fda.gov/medical-devices/medical-device-recalls/baxter-healthcare-corporation-recalls-novum-iq-syringe-pump-potential-underdosing?utm_medium=email&utm_source=govdelivery
Sanxin Single Use Sterile Syringes	Fresenius Medical Care	https://www.fda.gov/medical-devices/medical-device-recalls/fresenius-medical-care-recalls-sanxin-single-use-syringes-leakages?utm_medium=email&utm_source=govdelivery
SeQuent® Please Neo	B. Braun Melsungen AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19783
HistoCore PEGASUS and HistoCore Pegasus Plus	Leica Biosystems Nussloch GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19787
Quantum TTC Biliary Balloon Dilators	Wilson Cook Medical Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19788

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

DEFIGARD Touch7 monitor and defibrillator	SCHILLER Medical SAS	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19791
Surgical lighting system	STERIS Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=15&rid=19793
Kangaroo Enteral Feeding Pump Sets	Cardinal Health 200, LLC (Covidien)	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19795
Pressure Injectable Central Venous Catheters	Teleflex and Arrow International	https://www.fda.gov/medical-devices/medical-device-recalls/teleflex-and-arrow-international-recall-pressure-injectable-catheter-kits-mislabeling?utm_medium=email&utm_source=govdelivery
saline (0.9% sodium chloride) and sterile water medical products	Nurse Assist, LLC.	https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-brands-saline-and-sterile-water-medical-products-nurse-assist-because-they-may?utm_medium=email&utm_source=govdelivery
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE	Olympus Corporation of the Americas	ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19768
Tracheostomy Care and Cleaning Trays	Medline Industries Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19770
NIM TriVantage EMG Endotracheal Tube	Medtronic Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19777

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

The neonatal ventilator family SOPHIE	Fritz Stephan GmbH.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19779
Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds)	Medtronic SA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19781
A subset of Medtronic LINQ II™ Insertable Cardiac Monitoring Systems (LNQ22)	Medtronic Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19782
High Flow Insufflation Unit	Olympus	https://www.fda.gov/medical-devices/medical-device-recalls/olympus-recalls-olympus-high-flow-insufflation-unit-due-over-inflation?utm_medium=email&utm_source=govdelivery
Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T, Intera 1.5T Power/Pulsar, SmartPath to dStream for 1.5T	Philips Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19753
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19756
Maquet SAS' examination and surgical lights put into service	MAQUET Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19758
BRONCHOFIBERSCOPE, BRONCHOVIDEOSCOPE	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19759

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Tracheostomy Care Kit, Dressing Change Kit, and Tracheostomy Care Set	Busse Hospital Disposables	https://www.fda.gov/medical-devices/medical-device-recalls/busse-hospital-disposables-inc-recalls-care-trays-and-kits-containing-sterile-water-based-products?utm_medium=email&utm_source=govdelivery
AirFit and AirTouch masks	ResMed Ltd	https://www.fda.gov/medical-devices/medical-device-recalls/resmed-ltd-recalls-continuous-positive-airway-pressure-cpap-masks-magnets-due-possible-magnetic?utm_medium=email&utm_source=govdelivery
Ivenix Infusion System	Fresenius Kabi	https://www.fda.gov/medical-devices/medical-device-recalls/fresenius-kabi-usa-llc-recalls-ivenix-large-volume-pump-lvp-ivenix-infusion-system-due-mechanical?utm_medium=email&utm_source=govdelivery
Regard Operative Lap P&S Surgical Kit	ROi CPS, LLC	https://www.fda.gov/medical-devices/medical-device-recalls/roi-cps-llc-recalls-regard-operative-lap-ps-surgical-kit-due-possible-lack-sterility?utm_medium=email&utm_source=govdelivery
Equinox Shoulder System	Exactech	https://www.fda.gov/medical-devices/safety-communications/risks-exactech-equinox-shoulder-system-defective-packaging-fda-safety-communication?utm_medium=email&utm_source=govdelivery
Incidin OxyWipe S and Incidin OxyFoam S	Ecolab Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19878
Medfusion Model 3500 Syringe Infusion Pump	Smiths Medical	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19880
MR systems with 60cm wide bore	Philips Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19882

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Medfusion Model 3500 and Model 4000	Smiths Medical	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19883
HRIS Acetabular Cup Cut Tips	Stryker Howmedica Osteonics Corp	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19884
EVair and EVair 03 (Jun-Air) Compressors	GE HealthCare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19873
Mega Soft Universal Patient Return Electrodes	Megadyne Medical Product	https://www.fda.gov/medical-devices/medical-device-recalls/megadyne-medical-products-inc-recalls-mega-soft-universal-patient-return-electrode-due-reports?utm_medium=email&utm_source=govdelivery
EVair or EVair 03 (Jun-air) compressors	General Electric (GE)	https://www.fda.gov/medical-devices/letters-health-care-providers/potential-exposure-certain-chemicals-use-ge-healthcare-evair-and-evair03-compressors-certain?utm_medium=email&utm_source=govdelivery
HeartMate Touch Communication System	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19877
herpes simplex virus type 2 (HSV-2)		https://www.fda.gov/medical-devices/letters-health-care-providers/hsv-2-tests-genital-herpes-can-produce-false-reactive-results-letter-clinical-laboratory-staff-and?utm_medium=email&utm_source=govdelivery
Secufill Injection line	MEDEX	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19866

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Myval Transcatheter Heart Valve System	Meril Life Sciences Pvt. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=15&rid=19868
Centricity Critical Care (CCC), Centricity Anesthesia (CA), Centricity Anaesthesia (CA), Centricity High Acuity Anesthesia (CHA-A), Centricity High Acuity Critical Care (CHA-CC) products	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19870
Achieva 1.5T, Achieva 1.5T Conversion, Achieva 3.0T, Ingenia Ambition X, Intera 1.5T, and SmartPath to dStream for 1.5T	Philips Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19871
Q-Stress and X-Scribe Cardiac Stress Testing Systems	Welch Allyn, Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19872
Panorama 1.0T HFO	Philips North America LLC	https://www.fda.gov/medical-devices/medical-device-recalls/philips-north-america-llc-recalls-panorama-10t-hfo-due-risk-explosion-during-quench-procedure-caused?utm_medium=email&utm_source=govdelivery
n Medfusion Model 4000 and 3500	Smiths Medical	globalcomplaints@icumed.com
CooperSurgical LifeGlobal global® Media	CooperSurgical, Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19854

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

OPTEASE™ Retrievable Vena Cava Filter, OPTEASE™ Retrieval Catheter	Cordis Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19857
High Flow Insufflation Unit	Olympus Medical Systems Corp.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19862
HLS Sets	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19864
StealthStation S8 Application Version 2.0 and 2.0.1	Medtronic Navigation Inc.	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-navigation-inc-recalls-stealthstation-s8-application-version-20-and-201-due-software?utm_medium=email&utm_source=govdelivery
bronchofiberscopes and bronchovideoscopes	Olympus Corporation	https://www.fda.gov/medical-devices/medical-device-recalls/olympus-corporation-americas-recalls-bronchofiberscopes-and-bronchovideoscopes-because-they-can-lead?utm_medium=email&utm_source=govdelivery
MEGADYNE MEGA SOFT Universal and Universal Plus Reusable Patient Return Electrodes	Megadyne Medical Products Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19851
Hydrophobic acrylic pre-loaded intraocular lens	Cristalens Industrie	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19817
Surdial X	Nipro Corporation.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19822

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

ZOOM™ programmer	Boston Scientific Corp.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19824
Multiple products by Karl Storz	Karl Storz Endoscopy UK Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19826
INGENIO, VITALIO, and ADVANTIO pacemakers and INLIVEN, INTUA, and INVIVE cardiac resynchronization therapy pacemakers (CRT-Ps)	Boston Scientific Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=19829
Sensis, Sensis Vibe Hemo, Sensis Vibe Combo	Siemens Healthcare GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19832
Proclaim™ XR SCS and Proclaim™ Elite SCS System, Proclaim™ DRG Neurostimulation System, Infinity™ DBS System	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19834
MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue	Datascope Corp	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19835
Sapphire MT Infusion Pump, Sapphire Epidural Infusion Pump, and Sapphire Plus Infusion Pump	Eitan Medical Ltd	https://www.fda.gov/medical-devices/medical-device-recalls/eitan-medical-ltd-recalls-sapphire-infusion-pumps-failure-detect-air-line?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Alaris Infusion Pumps	Becton Dickinson (BD)/Carefusion	https://www.fda.gov/medical-devices/medical-device-recalls/becton-dickinson-bdcarefusion-303-recalls-alaris-infusion-pumps-due-compatibility-issues-cardinal?utm_medium=email&utm_source=govdelivery
Atlan	Draeger Medical Systems Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19808
ResMed Masks with Magnets and Potential Magnetic	ResMed Limited.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19810
BeneFusion nSP Syringe Pumps	Shenzhen Mindray Bio-Medical Electronics Co., Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19889
IC9-RS intracavitary probes	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19886
SoClean 2 and SoClean 3	SoClean, Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19892
Feb-24		
3M™ Surgical Clipper Blade Assembly	3M Health Care	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19893
Atrium Express Dry Suction Dry Seal Chest Drain	Maquet Cardiovascular, LLC	https://www.fda.gov/medical-devices/medical-device-recalls/maquet-cardiovascular-llc-recalls-atrium-express-dry-suction-dry-seal-chest-drain-containing-sterile?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Philips Respironics ventilators, BiPAP machines, and CPAP machines	Philips	https://www.fda.gov/medical-devices/recalled-philips-ventilators-bipap-machines-and-cpap-machines/problems-reported-recalled-philips-ventilators-bipap-machines-and-cpap-machines?utm_medium=email&utm_source=govdelivery
Monoject syringes	Cardinal Health	https://www.fda.gov/medical-devices/safety-communications/do-not-use-certain-cardinal-health-monoject-luer-lock-and-enteral-syringes-fda-safety-communication?utm_medium=email&utm_source=govdelivery
Optima Coil System	Balt Extrusion	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19894
Servo-n System	Maquet Critical Care AB	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19897
Bubble Sensor	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19900
MAMMOMAT Revelation system	SIEMENS	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19901
Duet External Drainage and Monitoring System, Interlink Injection Sites.	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19902
Surgilon Braided Nylon Suture	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19905

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

MiniMed 780G insulin pump.	Medtronic MiniMed	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19906
High Frequency Transport Phasitron Breathing Circuit Kits	Percussionaire	https://www.fda.gov/medical-devices/medical-device-recalls/percussionaire-recalls-high-frequency-transport-phasitron-breathing-circuit-kits-over-pressurization?utm_medium=email&utm_source=govdelivery
REANIBEX 100	Osatu S.Coop.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19909
Original Perfusor® Line	B Braun Medical Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19917
Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube	Medtronic XOMED, Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19918
Medfusion syringe pump	Smiths Medical ASD Inc	https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-asd-inc-recalls-medfusion-model-4000-syringe-pump-due-issues-associated-earlier?utm_medium=email&utm_source=govdelivery
BrightView, BrightView X, BrightView XCT	Philips	https://www.fda.gov/medical-devices/medical-device-recalls/philips-recalls-brightview-imaging-systems-due-detector-unexpectedly-falling?utm_medium=email&utm_source=govdelivery
Tige Fémorale EVOK® - Standard - Sans collerette - Cimentée - Cône 12/14 – Taille 8	Amplitude.	https://ansm.sante.fr/informations-de-securite/tige-femorale-evok-standard-sans-collerette-cimentee-cone-12-14-taille-8-amplitude

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Epix Universal Clip Applier	Applied Medical Resources Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19922
STERRAD 100NX Sterilizers and STERRAD NX Sterilizers	Advanced Sterilization Products Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19924
Arrow QuickFlash Radial Artery Catheterisation kits and Sets	Arrow International LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19926
LUISA, TIVAN LS, Life One	Lowenstein Medical GmbH &Co.KG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19930
EMG Endotracheal Tube	Medtronic	https://www.fda.gov/medical-devices/letters-health-care-providers/update-recommendations-certain-medtronic-electromyogram-endotracheal-tubes-and-risk-airway?utm_medium=email&utm_source=govdelivery
smartwatches or smart rings		https://www.fda.gov/medical-devices/safety-communications/do-not-use-smartwatches-or-smart-rings-measure-blood-glucose-levels-fda-safety-communication?utm_medium=email&utm_source=govdelivery
BioZorb Marker and BioZorb LP Marker		https://www.fda.gov/medical-devices/safety-communications/biozorb-markers-and-potential-risks-use-breast-tissue-fda-safety-communication?utm_medium=email&utm_source=govdelivery
electrical operating room tables		https://www.fda.gov/medical-devices/letters-health-care-providers/follow-instructions-safe-use-electrical-operating-room-tables-letter-health-care-providers?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Care Plus and Lullaby Incubators	GE Healthcare Private Ltd	https://www.fda.gov/medical-devices/medical-device-recalls/wipro-ge-healthcare-private-ltd-recalls-care-plus-care-plus-models-1000-4000-and-lullaby-incubators?utm_medium=email&utm_source=govdelivery
Hintermann Series H3 Total Ankle Replacement system	DT MedTech LLC	https://www.fda.gov/medical-devices/safety-communications/hintermann-series-h3-total-ankle-replacement-has-higher-expected-risk-device-failure-fda-safety?utm_medium=email&utm_source=govdelivery
EVair and Jun-air compressors	Datex-Ohmeda Inc	https://www.fda.gov/medical-devices/medical-device-recalls/datex-ohmeda-recalls-evair-air-compressors-due-formaldehyde-emissions-found-specific-conditions-when?utm_medium=email&utm_source=govdelivery
Medfusion model 3500 syringe pump	Smiths Medical ASD Inc	https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-asd-inc-recalls-medfusion-model-3500-syringe-pump-due-issues-associated-earlier?utm_medium=email&utm_source=govdelivery
ExactaMix Pro 1200 and the Pro 2400	Baxter Healthcare	https://www.fda.gov/medical-devices/medical-device-recalls/baxter-healthcare-recalls-exactamix-pro-1200-and-pro-2400-due-software-error?utm_medium=email&utm_source=govdelivery
Duet External Drainage and Monitoring System (EDMS)	Medtronic Neurosurgery	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-neurosurgery-recalls-duet-external-drainage-and-monitoring-system-catheter-tubing-due?utm_medium=email&utm_source=govdelivery
VOCSN Patient Breathing Package	Ventec Life Systems	https://www.fda.gov/medical-devices/medical-device-recalls/ventec-life-systems-recalls-vocsn-patient-breathing-package-pediatric-active-oxygen-blue?utm_medium=email&utm_source=govdelivery
Covidien Auto Suture Structural Balloon Trocar & Auto Suture Blunt Tip Trocar	Covidien LLC...	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20945

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Hydrophilic acrylic intraocular lenses CLARE, QUATUOREVO, CRISTAL, LUCIS Preloaded hydrophobic acrylic intraocular lenses ARTIS Y PL, ARTIS PL E	Cristalens Industrie	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20946
Madary Disposable Latex Examination Gloves	Madar rubber factory	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20950
Detachable EndoRetrieval Pouch	Molnlycke Health Care AB.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20951
Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20952
Sofslik sutures within Mölnlycke® Procedure Trays	Molnlycke Health Care AB.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20953
Mar-24		
Lower Extremity Pack	Windstone Medical Packaging, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/windstone-medical-packaging-inc-recalls-local-lower-extremity-pack-house-ocular-pack-and-closure-kit?utm_medium=email&utm_source=govdelivery
HeartMate Touch System	Abbott	https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-heartmate-touch-communication-system-unintentional-pump-start-and-stop?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Avanos Affected Devices Due to Nurse Assist, LLC Pre-Filled Syringe	Avanos Medical, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/avano-recalls-mic-gastric-jejunal-feeding-tube-kits-containing-sterile-water-based-products-under?utm_medium=email&utm_source=govdelivery
Madary Disposable Latex Examination Gloves	Madar rubber factory	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=15&rid=20955
Rad-G Devices	Masimo Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20956
Perseus A500	Draeger Medical Systems Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20958
CERVIOS chronOS Wedge-Shaped Cage	Synthes GmbH.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20959
Soltive SuperPulsed Laser System	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20962
AirLife Adult Manual Resuscitator	Vyair Medical, Inc..	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20963
Ureteral dilator	Coloplast	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=20976

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Cannulae	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20978
Astral 100/150 ventilator	ResMed Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20979
Multiva 1.5T	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20980
Stay Safe Catheter Extension Luer-Lock 25cm, 32cm & 40cm	Fresenius Medical Care.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20983
CADD-Solis Ambulatory Infusion Pumps	Smiths Medical..	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20984
Cardiohelp-i	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20985
Apr-24		
ARROW QuickFlash Radial Artery and Radial Artery/Arterial Line Catheterization Kits	Teleflex and Arrow	https://www.fda.gov/medical-devices/medical-device-recalls/teleflex-and-arrow-international-recall-arrow-quickflash-radial-artery-and-radial-arteryarterial?utm_medium=email&utm_source=govdelivery
PneuPac paraPAC Plus 300 and 310 Ventilator Kits	Smiths Medical	https://www.fda.gov/medical-devices/medical-device-recalls/smiths-medical-asd-recalls-pneupac-parapac-plus-300-and-310-ventilator-kits-malfunction-causing-non?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Cerenovus CEREBASE DA Guide Sheath	Medos International Sàrl	https://www.fda.gov/medical-devices/medical-device-recalls/medos-international-sarl-recalls-cerenovus-cerebase-da-guide-sheath-due-cracking-distal-catheter?utm_medium=email&utm_source=govdelivery
Airvo 2 and myAirvo 2	Fisher & Paykel Healthcare Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20987
Zimmer Periarticular Locking Plate System, Distal Lateral Fibula Locking Plate	Zimmer Biomet	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20989
HLS Sets	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20992
Airvo 2 and myAirvo 2	Fisher & Paykel Healthcare Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20987
Zimmer Periarticular Locking Plate System, Distal Lateral Fibula Locking Plate	Zimmer Biomet	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20989
HLS Sets	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20992
AVEIR™ VR LEADLESS PACEMAKERS	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20993

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

HeartMate II and HeartMate 3 Left Ventricular Assist System	Abbott/Thoratec Corp	https://www.fda.gov/medical-devices/medical-device-recalls/abbottthoratec-corp-recalls-heartmate-ii-and-heartmate-3-left-ventricular-assist-system-lvas-due?utm_medium=email&utm_source=govdelivery
Obsidio Embolic	Boston Scientific Corporation	https://www.fda.gov/medical-devices/medical-device-recalls/boston-scientific-recalls-obsidio-conformable-embolic-increased-bowel-ischemia-risk-when-used-lower?utm_medium=email&utm_source=govdelivery
Ivenix Infusion System (IIS)	Fresenius Kabi USA, LLC	https://www.fda.gov/medical-devices/medical-device-recalls/fresenius-kabi-usa-llc-recalls-ivenix-infusion-pump-lvp-software-anomalies-have-potential-cause?utm_medium=email&utm_source=govdelivery
DMD sodium hypochlorite 5.25%	Shifaa United for Medical Devices	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=15&rid=20996
Portex™ Blue Line Siliconised PVC Tracheotomy Tube	Smiths Medical International Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=21000
OLYMPUS Triangle Tip Electrosurgical Knives	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=21002
Surgical Tracecarts	DeRoyal	https://www.fda.gov/medical-devices/medical-device-recalls/deroyal-industries-inc-recalls-tracecarts-containing-16fr-urine-meter-foley-under-recall-nurse?utm_medium=email&utm_source=govdelivery
Tablo Hemodialysis System	Outset Medical, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/outset-medical-inc-recalls-certain-tablo-hemodialysis-systems-risk-patient-exposure-higher-allowable?utm_medium=email&utm_source=govdelivery

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

Stay-Safe Catheter Extension Sets and Stay-Safe/Luer Lock Adapte	Fresenius Medical Care	https://www.fda.gov/medical-devices/medical-device-recalls/fresenius-medical-care-recalls-stay-safe-catheter-extension-sets-and-stay-safeluer-lock-adapter-risk?utm_medium=email&utm_source=govdelivery
Perseus A500 anesthesia workstation	Draeger Inc	https://www.fda.gov/medical-devices/medical-device-recalls/draeger-inc-recalls-perseus-a500-anesthesia-system-risk-sudden-unexpected-shutdown-when-used-battery?utm_medium=email&utm_source=govdelivery
Nimbus infusion pump systems	InfuTronix, LLC	https://www.fda.gov/medical-devices/medical-device-recalls/infutronix-llc-recalls-nimbus-and-nimbus-ii-infusion-pump-systems-multiple-device-failures-may-cause?utm_medium=email&utm_source=govdelivery
Disposable Biopsy Needles (911933)	Elekta Instrument AB	https://www.fda.gov/medical-devices/medical-device-recalls/elekta-instrument-ab-recalls-disposable-biopsy-needle-kit-leksell-stereotactic-system-possibly?utm_medium=email&utm_source=govdelivery
Vercise Genus™ Deep Brain Stimulation (DBS) Implantable Pulse Generator IPG (IPG)	Boston Scientific Corp	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21004
Multiple products by Karl Storz	Karl Storz Endoscopy UK Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=21006
StealthStation S8 Application	Medtronic Navigation, Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21007
High Flow Insufflation Unit	Olympus Medical Systems Corp.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21008

**MEDICAL DEVICES
RECALL AND SAFETY NOTICE 2024**

HistoCore Pegasus and HistoCore Pegasus Plus	Leica Biosystems Newcastle	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21009
Synapse PACS	FUJIFILM Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21012