

**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
Amplatzer Steerable Delivery Sheath	Abbott	https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-amplatzer-steerable-delivery-sheath-increased-risk-air-embolism?utm_medium=email&utm_source=govdelivery
Impella Left Sided Blood Pumps	Abiomed	blood-pumps-risk-motor-damage-after-contact-transcatheter?utm_medium=email&utm_source=govdelivery
TruSignal sensors	GE HealthCare	sensors-issues-may-reduce-defibrillation-energy-expose-patients?utm_medium=email&utm_source=govdelivery
Aperlan Poka-Yoke Agent A & Aperlan Poka-Yoke Agent B	Geringe 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	cardioverter-defibrillators-icds-and-cardiac-resynchronization-therapy?utm_medium=email&utm_source=govdelivery
Claria MRI, Amplia MRI, Compia MRI, Viva, Brava CRT-Ds	Medtronic	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.	system-manifold-failure-may-cause-gas-leaks-and-interrupt?utm_medium=email&utm_source=govdelivery
Oxylog 3000 Plus	Draeger Medical	plus-emergency-and-transport-ventilators-risk-unexpected?utm_medium=email&utm_source=govdelivery

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Alcon Phaco Tips	Alcon Laboratories Inc...	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19620
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
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

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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
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	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	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
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	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.	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

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TJF-Q190V/Q290V/Q170V DUODENOSCOPE	Olympus Corporation of the Americas	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19806
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-
Cardinal Health Monoject	Cardinal Health	https://www.fda.gov/medical-devices/medical-device-recalls/cardinal-health-recalls-monoject-disposable-syringes-incompatibilities-syringe-
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-
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
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-
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-
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

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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
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-recalls-airfit-airtouch-masks-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-recalls-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/medical-device-recalls/exactech-recalls-equinox-shoulder-system-defective-packaging-fda-safety-communication?utm_medium=email&utm_source=govdelivery

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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
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	mega-soft-universal-patient-return-electrode-due-reports?utm_medium=email&utm_source=govdelivery
EVair or EVair 03 (Jun-air) compressors	General Electric (GE)	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)		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
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

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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	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
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.	stealthstation-s8-application-version-20-and-201-due-software?utm_medium=email&utm_source=govdelivery
bronchofiberscopes and bronchovideoscopes	Olympus Corporation	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
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

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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
Alaris Infusion Pumps	Becton Dickinson (BD)/Carefusion	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
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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	express-dry-suction-dry-seal-chest-drain-containing-sterile?utm_medium=email&utm_source=govdelivery

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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	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
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	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	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

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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	medtronic-electromyogram-endotracheal-tubes-and-risk-airway?utm_medium=email&utm_source=govdelivery
smartwatches or smart rings		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		electrical-operating-room-tables-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
Care Plus and Lullaby Incubators	GE Healthcare Private Ltd	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	replacement-has-higher-expected-risk-device-failure-fda-safety?utm_medium=email&utm_source=govdelivery
EVair and Jun-air compressors	Datex-Ohmeda Inc	compressors-due-formaldehyde-emissions-found-specific-conditions-when?utm_medium=email&utm_source=govdelivery
Medfusion model 3500 syringe pump	Smiths Medical ASD Inc	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	external-drainage-and-monitoring-system-catheter-tubing-due?utm_medium=email&utm_source=govdelivery
VOCSN Patient Breathing Package	Ventec Life Systems	patient-breathing-package-pediatric-active-oxygen-blue?utm_medium=email&utm_source=govdelivery

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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
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
Sofsluk sutures within Mölnlycke® Procedure Trays	Molnlycke Health Care AB.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20953
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Lower Extremity Pack	Windstone Medical Packaging, Inc	local-lower-extremity-pack-house-ocular-pack-and-closure-kit?utm_medium=email&utm_source=govdelivery
HeartMate Touch System	Abbott	communication-system-unintentional-pump-start-and-stop?utm_medium=email&utm_source=govdelivery
Avanos Affected Devices Due to Nurse Assist, LLC Pre-Filled Syringe	Avanos Medical, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/avanos-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

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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
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
April2024		
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	parapac-plus-300-and-310-ventilator-kits-malfunction-causing-non?utm_medium=email&utm_source=govdelivery
Cerenovus CEREBASE DA Guide Sheath	Medos International Sàrl	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

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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
HeartMate II and HeartMate 3 Left Ventricular Assist System	Abbott/Thoratec Corp	and-heartmate-3-left-ventricular-assist-system-lvas- due?utm_medium=email&utm_source=govdelivery
Obsidio Embolic	Boston Scientific Corporation	conformable-embolic-increased-bowel-ischemia-risk-when-used- lower?utm_medium=email&utm_source=govdelivery
Ivenix Infusion System (IIS)	Fresenius Kabi USA, LLC	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	hemodialysis-systems-risk-patient-exposure-higher- allowable?utm_medium=email&utm_source=govdelivery
Stay-Safe Catheter Extension Sets and Stay-Safe/Luer Lock Adapte	Fresenius Medical Care	catheter-extension-sets-and-stay-safeluer-lock-adapter- risk?utm_medium=email&utm_source=govdelivery
Perseus A500 anesthesia workstation	Draeger Inc	anesthesia-system-risk-sudden-unexpected-shutdown-when-used- battery?utm_medium=email&utm_source=govdelivery
Nimbus infusion pump systems	InfuTronix, LLC	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

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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
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
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SonarMed Airway monitoring system	SonarMed Inc	https://www.fda.gov/medical-devices/medical-device-recalls/sonarmed-inc-recalls-airway-monitors-due-software-anomaly-resulting-failure-detect-partial?utm_medium=email&utm_source=govdelivery
VITEK 2 AST cards	BioMérieux	https://www.fda.gov/medical-devices/medical-device-recalls/biomerieux-inc-recalls-vitek-2-ast-kit-due-incorrect-ceftriaxone-concentrations?utm_medium=email&utm_source=govdelivery
Sevoflurane vaporizers Vaporizer Sevoflurane, QUIK FIL, Vaporizer Isoflur, Maquet filling	Getinge Lancer	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21016
HeartSine Samaritan PAD	HeartSine Technologies Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21018
Infinity® Acute Care System (IACS) and Infinity M540 standalone configuration	Draeger Medical Systems Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21024
Medfusion™ 3500 and 4000 Syringe Pumps	Smiths Medical	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21026
Mojo Full Face Mask, Mojo 2 Full Face Mask, iQ 2 Nasal Mask, and Phantom 2 Nasal Mask.	Sleepnet	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21029
Version 2.7 of the Apple iOS t:connect mobile app used in	Tandem Diabetes Care, Inc	version-27-apple-ios-tconnect-mobile-app-used-conjunction-tslim-x2?utm_medium=email&utm_source=govdelivery
Getinge/Maquet cardiovascular medical devices:		getinge-cardiovascular-devices-letter-health-care-providers?utm_medium=email&utm_source=govdelivery

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Route 92 Medical products	Route 92 Medical Inc	https://www.fda.gov/medical-devices/medical-device-recalls/route-92-medical-inc-recalls-catheter-due-distal-tip-separation-proximal-marker-band?utm_medium=email&utm_source=govdelivery
Height Adjustable (HA) FlexTrak Trolley	Philips Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21031
NextSeq 550Dx / MiSeq Dx / NovaSeq 6000Dx / Illumina DRAGEN™ Server for NextSeq™ 550Dx / Illumina DRAGEN™ Server v4 / VeriSeq™ Onsite Server v2	Illumina Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21032
System Monitor used with the HeartMate™ Left Ventricular Assist System (LVAS).	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21033
Arrow FiberOptix Intra-Aortic Balloon Catheter Kit / Arrows UltraFlex Intra-Aortic Balloon Catheter Kit	Arrow International Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21034
ADVANTA VXT and FLIXENE VASCULAR GRAFTS	Atrium Medical Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21035
Real Intelligence CORI	Smith & Nephew Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21036
Medical devices with rechargeable batteries		https://www.fda.gov/medical-devices/consumer-products/tips-help-charge-medical-devices-safely-and-avoid-overheating?utm_medium=email&utm_source=govdelivery
Trilogy EVO, Trilogy EV300, Trilogy Evo O2, and Trilogy Evo Universal	Philips Respironics, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-inc-recalls-trilogy-evo-continuous-ventilators-due-software-related-possible?utm_medium=email&utm_source=govdelivery
Cue Health's COVID-19 Tests		https://www.fda.gov/medical-devices/safety-communications/do-not-use-cue-healths-covid-19-tests-due-risk-false-results-fda-safety-communication?utm_medium=email&utm_source=govdelivery
HeartMate 3 LVAS	Abbott	ventricular-assist-system-lvas-implant-kit-risk-blood-leakage-or-air?utm_medium=email&utm_source=govdelivery

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plastic syringes	Zhejiang Longde Pharmaceutical Co. Ltd. and Shanghai Kindly Enterprise Development Group Co.	https://www.fda.gov/medical-devices/safety-communications/update-evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication?utm_medium=email&utm_source=govdelivery
Power cords used with the Welch Allyn Connex ProBP 3400 Digital Blood Pressure Device and Welch Allyn Spot Vision Screener	Welch Allyn Inc. (Baxter)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21041
VICRYL™, VICRYL™ PLUS, PDS™, PDS™ PLUS, MONOCRYL™ AND MONOCRYL™ PLUS SUTURES	Ethicon Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21042
MobileDiagnost wDR	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21044
fabian HFO, fabian +nCPAP evolution, fabian Therapy evolution	Acutronic Medical Systems AG.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=21045
Deep Brain Stimulation (DBS) Clinician Programmer and DBS Patient Programmer applications.	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21046
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Biozorb Marker	Hologic, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/hologic-inc-recalls-biozorb-marker-due-complications-implanted-devices?utm_medium=email&utm_source=govdelivery
Twin Tube	Vyair Medical, Inc	https://www.fda.gov/medical-devices/medical-device-recalls/vyair-medical-inc-recalls-twin-tube-due-potential-nozzle-separating-during-patient-use?utm_medium=email&utm_source=govdelivery
Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21047
Ascenda™ Intrathecal Catheter	Medtronic Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21048
EIT PLIF	EIT Emerging Implant Technologies GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21051
Wired Avalon Ultrasound Transducer	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21053

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Nimbus II Plus infusion pumps	OptumHealth Care Solutions, LLC	nimbus-ii-infusion-pump-systems-under-recall-infutronix-llc?utm_medium=email&utm_source=govdelivery
2nd Generation CentriMag Primary Console	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21054
VasoView HemoPro Endoscopic Vessel Harvesting Systems	MAQUET Cardiopulmonary GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21059
multiFiltratePRO	Fresenius Medical Care.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21060
731 ZOLL Ventilators	ZOLL Medical Corporation	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21061
Mutars RS Stem and Mutars RS Extension Sleeve	Implantcast	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21062
MiniMed™ 600 and 700 series insulin pump	Medtronic SA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21063
SMD Disposable Infusion Set	SECURED MEDICAL DIRECTION UK CO., LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=15&rid=21064
S8 Application Versions 1.2.0, 1.1.0, 1.0.3, 1.0.2, and 1.0.1	Medtronic	application-versions-120-110-103-102-and-101-software-error-may?utm_medium=email&utm_source=govdelivery
Centricity High Acuity Anesthesia (CHA A) system	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21067
Plum Infusion Systems.	ICU Medical Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21068
Multiva 1.5T systems equipped with g-MDU	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21069
Sense XL Torso Coil	Philips Medical Systems	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21075
Sub-G Endotracheal Tube with Subglottic Suction	Medline Industries	industries-lp-removes-medline-sub-g-endotracheal-tube-subglottic?utm_medium=email&utm_source=govdelivery
Arrow FiberOptix Intra-Aortic Balloon Catheter Kit and Arrow UltraFlex Intra-Aortic Balloon Catheter Kits	Teleflex	https://www.fda.gov/medical-devices/medical-device-recalls/teleflexarrow-international-recall-arrow-fiberoptix-and-ultraflex-intra-aortic-balloon-iab-catheter?utm_medium=email&utm_source=govdelivery

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Vaporizer Sevoflurane Maquet Filling	Getinge	maquet-filling-risk-patient-and-health-care-professional?utm_medium=email&utm_source=govdelivery
MEGADYNE MEGA SOFT Pediatric Patient Return Electrodes	Megadyne	megadyne-mega-soft-pediatric-patient-return-electrodes-risk?utm_medium=email&utm_source=govdelivery
DEFIGARD HD-7	Schiller AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21076
IntelliVue Multi-Measurement Module X3	Philips Medizin Systeme GmbH	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21077
Aqualine family of tubing sets for Aquarius System	Haemotronic	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21078
Bivona® Neonatal/Pediatric and Adult Tracheostomy products	Smiths Medical International Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21079
Proclaim, Proclaim XR, Proclaim Elite SCS System and Proclaim DRG Neurostimulation System	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21080
Infinity DBS neurostimulation System	Abbott	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21081
Total Knee Arthroplasty (TKA) 2, Total Knee Arthroplasty (TKA) 1, Partial Knee Arthroplasty (PKA) 3, Total Hip Arthroplasty (THA) 4.0, 4.1 on Mako 3.0, 3.1.	Stryker Orthopaedics	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21082
Centrella max & pro+ Hospital Bed Surface	Hill Rom Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21084
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V30, A30, and A40 ventilators	Philips Respironics, Inc	respironics-inc-updates-use-instructions-bipap-v30-bipap?utm_medium=email&utm_source=govdelivery
731 ventilators	ZOLL Medical Corporation	corporation-updates-use-instructions-731-ventilators-due-missing?utm_medium=email&utm_source=govdelivery
HeartMate System Monitor	Abbott Medical	monitor-correction-abbott-medical-issues-correction-heartmate?utm_medium=email&utm_source=govdelivery
OmniLab Advanced+ (OLA+) Ventilator	Philips Respironics	respironics-inc-updates-use-instructions-omnilab-advanced?utm_medium=email&utm_source=govdelivery

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Trilogy Evo, Trilogy Evo O2, and Trilogy EV300	Respironics Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21089
BeneHeart D1 Automated External Defibrillator	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21091
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=21092
BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro	Respironics Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21095
SPACEPLUS INFUSOMAT	B. Braun Melsungen AG.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21097
Trevo Retrievers/Microcatheters, FlowGate2, Distal Access Catheter (DAC) and Synchro	Stryker Neurovascular	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21099
CUSA Excel C2600 23kHz Straight Handpiece	Integra LifeSciences	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21101
BeneHeart C2	Shenzhen Mindray Bio-Medical Electronics Co., Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21102
Implantable Pulse Generator (IPG) Model 3028	Inspire Medical Systems Inc	stimulator-device-removal-inspire-medical-systems-inc-removes-inspire?utm_medium=email&utm_source=govdelivery
SENSE XL Torso (1.5T and 3.0T) coils	Philips North America LLC	north-america-llc-updates-use-instructions-sense-xl-torso?utm_medium=email&utm_source=govdelivery
iLED 7 Surgical Light systems	Baxter Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21106
Synchro Guidewires	Stryker Neurovascular	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21108
Puritan Bennett™ 500 Series Ventilators	Covidien LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21110
Capio SLIM Suture Capturing Device	Boston Scientific Corp	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21114
Arctic Sun 5000	Becton Dickinson & Co. (BD)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21116

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NIM Vital Nerve Monitoring System	Medtronic XOMED, Inc	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21117
Fassier-Duval Telescopic IM System (FRT250 – 4.0-6.4 CARTRIDGE)	OrthoPediatrics Corp	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21118
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=21119
NIM Standard and Contact EMG endotracheal tubes	Medtronic	standard-and-contact-emg-endotracheal-tubes-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
BD BACTEC blood culture media bottles		blood-culture-media-bottles-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
MEGA SOFT, MEGA SOFT DUAL, and MEGA 2000 Patient Return Electrodes	Megadyne	https://www.fda.gov/medical-devices/medical-device-recalls/electrode-pad-correction-megadyne-issues-correction-mega-soft-mega-soft-dual-and-mega-2000-patient?utm_medium=email&utm_source=govdelivery
HAMILTON-C6 Medical Ventilator	Hamilton Medical	medical-issues-correction-hamilton-c6-medical-ventilators?utm_medium=email&utm_source=govdelivery
	Amplitude.	https://ansm.sante.fr/informations-de-securite/prothese-intermediaire-de-hanche-orthopedie-cupule-intermediaire-spheric-sans-ciment-taille-48-28-amplitude
CPT Hip System Femoral Stem 12/14 Neck Taper	Zimmer Biomet	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21121
BLUperc® Percutaneous Dilation Tracheostomy Kit	Smith's Medical International Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21122
PST 500 U Precision Surgical Table	Baxter Healthcare.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21123
HeartStart Intrepid Monitor/Defibrillator	Philips Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21124
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=21125
DLP™ Single Stage Venous Cannulae with right angle metal tip	Medtronic Inc.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21126

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Life200 Ventilator System	Baxter	https://www.fda.gov/medical-devices/medical-device-recalls/ventilator-recall-baxter-removes-life2000-ventilator-due-potential-failure-battery-charging-dongle?utm_medium=email&utm_source=govdelivery
I-Pack Injection Kits	Bausch + Lomb	lombsynergetics-inc-removes-certain-i-pack-injection-kits-due?utm_medium=email&utm_source=govdelivery
plastic syringes made in China		made-china-potential-device-failures-fda-safety-communication?utm_medium=email&utm_source=govdelivery
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Mega 2000 and Mega Soft Patient Return Electrodes	Megadyne Medical Products, Inc.	and-mega-soft-patient-return-electrodes-letter-health-care-providers?utm_medium=email&utm_source=govdelivery
HeartMate 3 LVAS	Abbott..	https://ade.sfda.gov.sa/Fsca/PublishDetails/40
McGRATH MAC video laryngoscope	Medtronic SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/44
V90 electronic vaporizer (for used with A9 Anesthesia system)	Shenzhen Mindray BioMedical Electronics Co.,	https://ade.sfda.gov.sa/Fsca/PublishDetails/45
NOVOSYN CHD	B Braun Surgical SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/35
CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pumps	Smiths Medical	correction-smiths-medical-issues-correction-cadd-solis-and-cadd?utm_medium=email&utm_source=govdelivery
NIM Vital Nerve Monitoring System	Medtronic	medtronic-issues-correction-nim-vital-nerve-monitoring-system-due?utm_medium=email&utm_source=govdelivery
Cardiac Science Corporation	ZOLL Powerheart G5 AED, SemiAutomatic	https://ade.sfda.gov.sa/Fsca/PublishDetails/53
Portex™ Blue Line Siliconised PVC Tracheotomy Tube	Smiths Medical International Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/58
Erytra Eflexis	Grifols	CTSTechnical_Documentation@grifols.com
BLUSelect®, BLUgriggs® and BLUperc® products	Smiths Medical, Inc	globalcomplaints@icumed.com
VERCISE GENUS R16 IPG KIT - VERCISE GENUS R32 IPG KIT	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishDetails/64
Airvo 3	Fisher & Paykel Healthcare Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/63
Aisys CS2, Avance CS2, Avance	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/62
DAILIES TOTAL1, DAILIES TOTAL1 for Astigmatism	Alcon Laboratories Inc....	https://ade.sfda.gov.sa/Fsca/PublishDetails/65

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HMC feeding, aspiration and feeding/aspiration tubes	HMC PREMEDICAL SPA	https://ade.sfda.gov.sa/Fsca/PublishDetails/69
Impella CP	ABIOMED Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/67
Plum 360, Plum A+ and Plum A+3 Infusion Systems	ICU Medical	medical-updates-instructions-use-regarding-batteries-plum-360?utm_medium=email&utm_source=govdelivery
RMU-2000 ARM XR Chest Compression Devices	Defibtech, LLC	defibtech-llc-removes-rmu-2000-arm-xr-chest-compression-device-due?utm_medium=email&utm_source=govdelivery
ClotTrier XL Catheter	Inari Medical	medical-updates-use-instructions-clottrier-xl-catheter-due?utm_medium=email&utm_source=govdelivery
High Flow Insufflation Unit	Olympus Corporation of the Americas	https://ade.sfda.gov.sa/Fsca/PublishDetails/76
Hookup	STERIS Corporation...	https://ade.sfda.gov.sa/Fsca/PublishDetails/73
Level 1 Fast Fluid Flow Fluid Warmers and Level 1 NORMOFLO Irrigation Fluid Warmers	Smiths Medical International Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/79
Vanta™ Implantable Neurostimulator	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/78
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CADD-Solis Li-ion Rechargeable Battery Packs	Smiths Medical..	https://ade.sfda.gov.sa/Fsca/PublishDetails/84
EasyConnect Adapter for 2 to 4 Lumen Jet Catheter	CARL REINER GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/87
Single Patient Use Circuits and Blue Ventilator Adapter Assemblies	Baxter	healthcare-corporation-recalls-certain-volara-system-single?utm_medium=email&utm_source=govdelivery
McGrath MAC Video Laryngoscope	Medtronic	certain-mcgrath-mac-video-laryngoscopes-updates-use?utm_medium=email&utm_source=govdelivery
FreeStyle Libre 3 sensors	Abbott Diabetes Care Inc	sensor-recall-abbott-diabetes-care-inc-issues-recall-certain?utm_medium=email&utm_source=govdelivery
Vivo 45 LS ventilators	Breas Medical	updates-use-instructions-in-vivo-45-ls-due-potential-elevated?utm_medium=email&utm_source=govdelivery
Automated Compounding Device Inlet	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/97
CADD-Solis AC Adapter	Smiths Medical.	https://ade.sfda.gov.sa/Fsca/PublishDetails/91

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IntelliVue Patient Monitor Power Supply	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/93
Ivenix LVP Primary Administration Sets	Fresenius Kabi	fresenius-kabi-usa-removes-certain-ivenix-large-volume-pump?utm_medium=email&utm_source=govdelivery
Hip System Femoral Stem 12/14 Neck Taper	Zimmer Biomet	stem-and-increased-risk-thigh-bone-fracture-fda-safety?utm_medium=email&utm_source=govdelivery
Space Infusion System/Large Volume Pump	B. Braun Medical Inc.	medical-inc-issues-correction-Infusomat-space-infusion-systemlarge?utm_medium=email&utm_source=govdelivery
Bivona Neonatal/Pediatric and Adult Tracheostomy tubes	Smiths Medical	https://www.fda.gov/medical-devices/medical-device-recalls/tracheostomy-tube-recall-smiths-medical-removes-certain-bivona-neonatalpediatric-and-adult?utm_medium=email&utm_source=govdelivery
paraPAC plus P300 and P310 ventilators	Smiths Medical	parapac-plus-ventilators-due-loosened-or-detached-patient?utm_medium=email&utm_source=govdelivery
Allurion Device / Eclipse Gastric Balloon System	Allurion technologies inc..	https://ade.sfda.gov.sa/Fsca/PublishDetails/114
Giraffe OmniBed and Giraffe OmniBed Carestation devices	Datex - Ohmeda Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/107
MEERA CL	MAQUET Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/109
Olympus BF-H1100 and BF1TH1100 Bronchovideoscopes, and Olympus EVIS EXERA III SIFH190 Small Intestinal Videoscope	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/115
-SOLTIVE Pro SuperPulsed Laser System - SOLTIVE Premium SuperPulsed Laser System	Olympus Corporation of the Americas	https://ade.sfda.gov.sa/Fsca/PublishDetails/108
Spaceplus Perfusor	B. Braun Melsungen AG.	https://ade.sfda.gov.sa/Fsca/PublishDetails/103
Trilogy Evo and Trilogy Evo O2 Ventilators	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/113
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paraPAC Plus P300 and P310 ventilator	Smiths Medical	issues-correction-parapac-plus-p300-and-p310-ventilators-due?utm_medium=email&utm_source=govdelivery

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Ivenix Infusion System Large Volume Pump (LVP)	Fresenius Kabi USA, LLC	fresenius-kabi-usa-llc-issues-correction-ivenix-infusion-system?utm_medium=email&utm_source=govdelivery
Trilogy Evo, Trilogy EV300, Trilogy Evo O2, and Trilogy Evo Universal ventilators t	Philips Respironics	https://www.fda.gov/medical-devices/medical-device-recalls/ventilator-software-correction-philips-respironics-issues-mandatory-software-correction-and-updates?utm_medium=email&utm_source=govdelivery
Phasitron 5 In-Line Valve	Sentec/Percussionaire	sentecpercussionaire-updates-use-instructions-phasitron-5-line-valve?utm_medium=email&utm_source=govdelivery
Automated Compounding Device Inlets (disposable inlet)	Baxter Healthcare	baxter-healthcare-corporation-updates-use-instructions-exactamix?utm_medium=email&utm_source=govdelivery
McGRATH MAC video laryngoscope	Medtronic SA	https://ade.sfda.gov.sa/Fsca/PublishDetails/119
Spacelabs DM4 Ultraview DM3	Spacelabs Healthcare Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/121
Atlan A100 Atlan A300 Atlan A300 XL Atlan A350 Atlan A350 XL	Draeger Medical Systems Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/132
paraPAC 300 paraPAC plus 310	Smiths Medical..	https://ade.sfda.gov.sa/Fsca/PublishDetails/131
Pneupac paraPAC	Smiths Medical..	https://ade.sfda.gov.sa/Fsca/PublishDetails/129
TruSystem 7000 Surgical Table	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/127
UroPass- Ureteral Access Sheath	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/130
MiniMed 600 and 700 series insulin pumps	Medtronic	
Obsidio Conformable Embolic	Boston Scientific	
BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/142
BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/138
Ophthalmic viscosurgical device	Hyaltech Ltd	https://ade.sfda.gov.sa/Fsca/PublishDetails/141
POLARX BALLOON CATHETER (multiple models	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishDetails/144

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Q-FLOW SOLO, Q-FLOW DUO, Q-FLOW TRIO, Q-FLOW QUAD, Q-FLOW MOBILE	Merivaara Corp	https://ade.sfda.gov.sa/Fsca/PublishDetails/143
single Use Biopsy Valve	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/140
Tracheal Tube Introducer Woven Coude Tip 15CH 60cm. Tracheal Tube Guide Woven Straight 15CH 70cm. Tracheal Tube Guide Woven Straight 10CH 70cm	Smiths Medical International Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/137
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BLUSelect, BLUgriggs, and BLUperc products	Smiths Medical	usfda@public.govdelivery.com
BioZorb Markers and BioZorb LP Markers	Hologic Inc	usfda@public.govdelivery.com
Jaco assistive robotic arm	Kinova	usfda@public.govdelivery.com
EVair Compressor	GE HealthCare	usfda@public.govdelivery.com
3M™ V.A.C.® Ulta Therapy Unit	KCI USA Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/155
AK 98 hemodialysis machines	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/159
Alinity ci-series System Control Module (SCM)	Abbott	https://ade.sfda.gov.sa/Fsca/PublishDetails/157
GIF-1TH190 Gastrointestinal Videoscope	Olympus Europa SE & CO.KG..	https://ade.sfda.gov.sa/Fsca/PublishDetails/149
Codman Surgical Patties	Integra LifeSciences Production Corporation	https://ade.sfda.gov.sa/Fsca/PublishDetails/151
Level 1 DI-50 Normothermic I.V. Fluid Administration Sets	Smiths Medical International Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/145
Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/148
Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/156
MiniMed Insulin Pumps	Medtronic MiniMed...	https://ade.sfda.gov.sa/Fsca/PublishDetails/153

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Philips OmniWire Pressure Guide Wire	VOLCANO CORPORATION	https://ade.sfda.gov.sa/Fsca/PublishDetails/150
Vue PACS	Philips Medical Systems Nederland B.V.,	https://ade.sfda.gov.sa/Fsca/PublishDetails/146
Giraffe OmniBed and Giraffe OmniBed CareStation	GE HealthCare	usfda@public.govdelivery.com
Phasitron 5 breathing circuits	Percussionaire	usfda@public.govdelivery.com
- Aggressive Cutter, sterile Full Radius Resector, sterile - Aggr. Pro Line Shaver Blade, sterile - Round Burr, sterile - Aggressive Barrel Burr, sterile - Finish Barrel Burr, sterile - Semi Hooded Barrel Burr, sterile - Aggressive Barrel Burr, ste	KARL STORZ SE & Co. KG	https://ade.sfda.gov.sa/Fsca/PublishDetails/167
NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/164
Safari Discovery Series Latex medical examination gloves	TG MEDICAL SDN. BHD.	https://ade.sfda.gov.sa/Fsca/PublishDetails/165
AMS 800™, sphincter urinaire artificie	Boston Scientific	https://ansm.sante.fr/informations-de-securite/sphincter-urinaire-artificiel-ams-800-boston-scientific
evaluation of the potential for exposure to airborne chemicals	U.S. Food and Drug Administration (FDA)	usfda@public.govdelivery.com
Argus 717V - Argus 718V	Codan Argus AG	https://ade.sfda.gov.sa/Fsca/PublishDetails/174
Becker and Exacta external drainage and monitoring systems (EDMS)	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/175
EVair and EVair 03 (Jun-Air)	Datex - Ohmeda Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/170
Infusomat Space Line	B Braun Medical Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/171
Philips MR system breast coils	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/173
Proteus XR/a	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/168

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ParaPAC plus™ Model 300 and Model 310 Ventilator	Smiths Medical	ncmdr.md@sfda.gov.sa
Getinge/Maquet VasoView HemoPro Endoscopic Vessel Harvesting (EVH) Systems	Getinge/Maquet	usfda@public.govdelivery.com
ACURATE neo2™ Aortic Valve Systems	Boston Scientific Corp.	https://ade.sfda.gov.sa/Fsca/PublishDetails/183
Cordis SELUTION SLRTM 018 PTA 3.0 mm X 100 mm Balloon Catheters	Cordis Corporation,	https://ade.sfda.gov.sa/Fsca/PublishDetails/181
SIL-1000-S, SIL-2000-S, SIL5000-S Silicone Oil - Prefilled 10ml syringes	D.O.R.C. Dutch Ophthalmic Research Center	https://ade.sfda.gov.sa/Fsca/PublishDetails/180
VITRA 810	Quantel Medical	https://ade.sfda.gov.sa/Fsca/PublishDetails/184
CADD-Solis Li-ion Rechargeable Battery Packs	Smiths Medical	usfda@public.govdelivery.com
Trilogy Evo, Trilogy Evo O2, Trilogy EV300, Trilogy Evo Universal, Aeris EVO, Garbin Evo, and LifeVent EVO2 devices	Philips	usfda@public.govdelivery.com
Atlan A100 Atlan A300 Atlan A300 XL Atlan A350 Atlan A350 XL	Draeger Medical Systems Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210599
FreeStyle Comfort Oxygen Concentrator	Caire Inc..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210663
Sophie und Sophie 2020	Fritz Stephan GmbH.	24_kundeninfo_en.pdf?__blob=publicationFile
Cook Medical Hemo-7 Hemospray Endoscopic Hemostat. Hemo-10 Hemospray Endoscopic Hemostat	Wilson-Cook Medical Inc.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2024/38017-24_kundeninfo_en.pdf?__blob=publicationFile
MEDRAD Centargo CT Injection System	Imaxeon Pty Ltd	https://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2024-RN-01021-1
Philips Spectral CT systems or the Spectral CT on Rails systems	Philips Healthcare	https://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2024-RN-01022-1

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Battery corpuls aed	S Elektromedizinische Geräte G. Stemple Gm	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2024/38536-24_kundeninfo_en.pdf?__blob=publicationFile
Olympus BF-H1100 and BF-1TH1100 Bronchovideoscopes, and Olympus EVIS EXERA III SIF-H190 Small Intestinal Videoscope	Olympus Corporation of the Americas	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210743
The Acrobat-i Stabilizer z and Positioner z	MAQUET Cardiovascular LLC.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210771
NovoHip Total Hip System	Novosource, LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210738
OPRA Surgical System Femur Abutment F-Platform	Integrum	https://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2024-RN-00992-1
Thoraflex Hybrid	Terumo Cardiovascular Systems Corporation	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2024/39731-24_kundeninfo_en.pdf?__blob=publicationFile
EnChroma Safety Glasses with Rx Indoor Universal Lenses	Enchroma Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210336
Axillary Insertion Introducer	Oscor Inc...	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210336
EZ Glide Aortic Cannulae	Edwards Lifesciences	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210336
HALYARD* PUREZERO* Limon* Nitrile Exam Gloves	O&M Halyard	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/02/2024/40223-24_kundeninfo_en.pdf?__blob=publicationFile
Instinct Plus Endoscopic Clipping Device	Wilson-Cook Medical Inc	https://apps.tga.gov.au/PROD/SARA/arn-detail.aspx?k=RC-2024-RN-01006-1
Marquee Disposable Core Biopsy Instruments	Bard Peripheral Vascular Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210375
Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210539
MONOCRYL	Ethicon Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210679
Multiple products	AVID Medical, Inc...	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210636
Navitor Transcatheter Aortic Heart Valves	Abbott Medical	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=210825
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Disposable Biopsy Needle Kit	Elekta	usfda@public.govdelivery.com
microTargeting Insertion Tube Sets	FHC Inc	usfda@public.govdelivery.com

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PD Transfer Sets	Baxter	usfda@public.govdelivery.com
AVEIR™ DR Leadless Pacemaker (LP) System	Abbott..	https://ade.sfda.gov.sa/Fsca/PublishDetails/195
CARESCAPE R860 Ventilators, and Engström Carestation and Engström PRO Ventilators	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/200
Sophie und Sophie 2020 neonatal ventilator	Fritz Stephan GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/199
Monoject U-100 1 mL Insulin Syringe	Cardinal Health	usfda@public.govdelivery.com
- Tec 6 Plus - Tec 820 ISO - Tec 820 SEV - Tec 850 ISO - Tec 850 SEV	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/205
Carestation 620/650/650c (with software version 02SP02,02SP03,02SP04 or 02SP05)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/202
HeartStart Intrepid	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/210
REACH - Magnum Stapler	Reach Surgical INC.	https://ade.sfda.gov.sa/Fsca/PublishDetails/204
Ivenix large-volume pumps (model LVP-0004; UDI 00811505030320)	Fresenius Kabi USA	usfda@public.govdelivery.com
Sense XL Torso Coil	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishDetails/216
Sterile Percutaneous Pin	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishDetails/211
Accolade pacemaker devices	Boston Scientific Corporation	https://www.fda.gov/medical-devices/safety-communications/accolade-pacemaker-devices-boston-scientific-and-potential-need-early-device-replacement-fda-
Biozorb Marker	Hologic, Inc	removes-biozorb-3d-bioabsorbable-markers-due-risk-patient?utm_medium=email&utm_source=govdelivery
POLARx and POLARx FIT	Boston Scientific	updates-use-instructions-polarx-and-polarx-fit-cryoablation?utm_medium=email&utm_source=govdelivery
endoscope sheaths	Trokamed	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-nephroscope-sheath-issue-trokamed-gmbh?utm_medium=email&utm_source=govdelivery

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CSB batteries	ICU Medical	https://www.fda.gov/medical-devices/infusion-pump-battery-recall-icu-medical-removes-some-csb-batteries-intended-use-plum-360-and-a3?utm_medium=email&utm_source=govdelivery
MAJ-891 Forceps/Irrigation Plug	Olympus	https://www.fda.gov/medical-devices/medical-device-recalls/early-alert-endoscope-accessories-forcepsirrigation-plug-issue-olympus?utm_medium=email&utm_source=govdelivery
Certain Infinia, VariCam/VG/VH, Brivo NM 615, Discovery NM 630, Discovery NM/CT 670, and Optima NM/CT 640 Nuclear Medicine systems	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/220
Getinge/Maquet sevoflurane vaporizers	Getinge Lancer	https://ade.sfda.gov.sa/Fsca/PublishDetails/218