



SBED Weekly Update

02-Sep-15

Dear,

SBED team is pleased to inform you that **55** new FSCA/recalls posted on [SFDA website](#)

(Please note: below list of FSCA/ recalls for the period of 8/24/2015 to 8/30/2015

In order to view more details, click the links and for ECRI alerts see the attachments

NOTE:

FSCA / Recalls are classified into three categories, representing the potential risk to public health: Class I : High Risk, Class II : Medium Risk and Class III: Low Risk.

FSN (Field Safety Notice) : A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Active Implantable Devices

New	RF enabled St. Jude Medical Ellipse, Fortify Assura, Unify Assura, and Quadra Assura Implantable Cardioverter Defibrillators (ICDs) and Assurity and Allure Pacemakers when used with Merlin@home RF Remote Monitoring Transmitter Model EX1150	8/25/2015	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	http://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?c
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Anaesthetic and respiratory devices

New	MEDUMAT Transport ventilator	8/27/2015	Weinmann.	Al Khateeb United Trading Est.	FSN	http://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
Update	Optional Power Supply Unit PS500	8/30/2015	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	http://nc

Assistive products for persons with disability

New	Ascot Bath with Transfer Seat	8/25/2015	Gainsborough	N/A	FSN	http://nc
New	Invacare Pronto Air Personal Transporter	8/27/2015	Invacare Corporation..	Nahdi Medical Company	2	http://nc
New	JCM compact bases used with Triton and Neptune seats	8/25/2015	Sunrise Medical	Al-Enayah Company	FSN	http://nc mdr
New	Transition gate manual in combination with Reda ceiling lift unit or trolley HCS5 / HCS37	8/30/2015	Handicare Ltd	Al Safwa Dimensions	1	http://nc mdr sfda

Dental devices

New	Narrow Right Angle Large Driver Tip (Hexed)	8/27/2015	Biomet 3i Inc	Asnan Medical Services	1	http://nc
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Diagnostic and therapeutic radiation devices

New	RayStation 4.7	8/30/2015	RaySearch Laboratories AB	N/A	2	http://nc A/Ca
New	Brilliance 64, Ingenuity CT, Ingenuity Core, and Ingenuity Core128 with the following versions: (Computed tomography (CT) full-body diagnostic X-ray system)	8/25/2015	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	2	http://nc mdr sfda gov.s a/Se cure/
New	Cios Alpha mobile C-arm x-ray System.	8/27/2015	SIEMENS	Siemens Medical Solutions	FSN	http://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	GE Optional Laser Centering Device X-ray generator.	8/30/2015	GE Healthcare	GE Healthcare	2	http://nc.mdr
New	Gemini Cabinet Xray system	8/27/2015	American Science & Engineering, Inc.	N/A	2	http://nc
New	Philips Ingenuity TF PET/MR system	8/25/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	http://nc
New	RadPro 40kW Digital X-Ray Panel and Mobile/Portable Diagnostic X-Ray	8/30/2015	Sedecal S.A	N/A	2	http://nc.mdr.sfda
New	Siemens Symbia T Series, Siemens Intevo Series system, Siemens Symbia S Series system	8/27/2015	SIEMENS	Siemens Medical Solutions	2	http://nc.mdr.sfda
New	XiO Radiation Treatment Planning Systems	8/30/2015	Elekta Inc	Analysis Device For Medical and Scientific	FSN	http://nc

Electro mechanical medical devices

New	Alaris Syringe Pump, Model No. 8110	8/30/2015	CareFusion 206 Inc,	Saudi Import Co. Banaja	1	http://nc
New	Atrium 36Fr Right Angled Firm PVC Thoracic Catheter	8/27/2015	Atrium Medical Corporation	Gulf Medical Co.	2	http://nc.mdr
New	Compoflex and Composelect bloodbag systems	8/27/2015	Fresenius Kabi Ltd	gulf Medical Co.	FSN	http://nc.mdr
Update	Fresenius NaturaLyte Bicarbonate Concentrate Bottles	8/30/2015	Fresenius Medical Care	Saudi Renal Services Ltd.	2	http://nc.mdr

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	LX3 Microscope Floor Stand used with the LuxOR Ophthalmic Microscope and LuxOR Ophthalmic Microscope with Q-VUE 3D Assistant Visualisation	8/27/2015	Alcon Laboratories Inc	AL-KAMAL Import	1	http://ncmdr.sfda.gov.sa/Secure/
New	Synthes Battery Power Line II Oscillator	8/27/2015	The Anspach Effort, Inc.	Al-Nozha Medical Est	2	http://ncmdr.sfda.gov.sa/Secure/
New	TRITON™ Pneumatic High Torque Hand Piece Hose	8/24/2015	Medtronic Inc	Gulf Medical Co.	FSN	http://ncmdr.sfda.gov.sa/Secure/

Healthcare facility products and adaptations

New	NEPTUNE® 2 WASTE MANAGEMENT SYSTEM, Actuator Assemblies	8/24/2015	Stryker Instruments.	Zimmo Trading Establishment.	FSN	http://ncmdr.sfda.gov.sa/Secure/
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In vitro diagnostic devices

New	B·R·A·H·M·S Calcitonin RIA	8/25/2015	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	FSN	http://ncmdr.sfda.gov.sa/Secure/
New	ADVIA Centaur XPT	8/25/2015	SIEMENS	Siemens Medical Solution	1	A/Ca\
Update	Dade Activated Cephaloplastin Reagent	8/25/2015	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	http://ncmdr.sfda.gov.sa/Secure/
New	IDYLLA KRAS MUTATION TEST	8/25/2015	Biocartis	N/A	FSN	http://ncmdr.sfda.gov.sa/Secure/
New	Leica ASP6025	8/24/2015	Leica Microsystems, Inc.	Salehiya Trading Est.	FSN	A/Ca\
New	Medidrug ALC VB	8/27/2015	DEM Diagnostica GmbH &	N/A	FSN	A/Ca\
New	N Latex β2-Microglobulin & DV Flex Reagent B2MIC	8/24/2015	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	http://ncmdr.sfda.gov.sa/Secure/

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	S2 Fluid Pack as a part of the cobas b221 Roche OMNI S systems	8/27/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	2	http://nc.mdr
New	Salter Labs NebuTech nebulizer	8/25/2015	Salter Labs..	yasmin albilali trading est	FSN	http://nc
New	Supplementary Reagents for CFT (Sheep Blood),	8/25/2015	SIEMENS	Siemens Medical Solutions	FSN	http://nc
New	VERSATREK AUTOMATED MICROBIAL DETECTION SYSTEM	8/24/2015	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	FSN	http://nc.mdr
New	Wall Chart for STERRAD 100NX System	8/27/2015	Advanced Sterilization Products	FAROUK, MAAMOUN TAMER & COMPANY	2	http://nc

Non-active implantable devices

New	Concave Reamer Head, Cannulated Drill Bit	8/27/2015	Trilliant Surgical Ltd	N/A	2	http://nc
New	Dual Port/Single Bladder Disposable Tourniquet Cuff	8/27/2015	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	http://nc.mdr
New	Genium X3	8/27/2015	ock Healthcare Products C	Al Gaim Comm. Est.	2	A/Ca
New	Link Endo-Modell Tibial Plateau Sets" and "Link Endo-Modell Replacement Sets	8/27/2015	Waldemar LINK GmbH & Co	Abdul Jaleel Ibrahim Batterjee Sons Development Co. Ltd.	FSN	http://nc.mdr.sfda
New	PROFEMUR® Neck Var/Val Long CoCr	8/25/2015	MicroPort Orthopedics	N/A	FSN	http://nc
New	Tibial Nail Wrap Holds 11 Nails and Synthes Intramedullary Nail Wrap Holds 10 Nails	8/27/2015	Synthes Inc	Isam Economic Co.	2	http://nc.mdr.sfda

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	WATCHMAN® Left Atrial Appendage Closure Device with Delivery System and WATCHMAN® Access System Access Sheath with Dilator	8/30/2015	Boston Scientific Corporation..	Medical Technology Establishment	FSN	http://ncmdr.sfda.gov.sa/Secure/CA/CAView

Reusable devices

New	certain Medrad® Mark 7 Arterion® Injection Systems	8/27/2015	Bayer Healthcare LLC..	Scientific & Medical Equipment House	FSN	http://ncmdr
New	Scholl compression hosiery	8/25/2015	Reckitt Benckiser Healthcare	N/A	FSN	http://nc
New	sterile electrodes	8/25/2015	Zethon Ltd	N/A	FSN	A/CA

Single-use devices

New	Celsite Implantable Access Port System	8/27/2015	B Braun ...	FAROUK, MAAMOUN TAMER & COMPANY	2	http://nc
New	CIDEX® OPA Solution Instructions For Use	8/25/2015	Advanced Sterilization Products	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http://nc
New	High pressure stopcocks	8/25/2015	ArcRoyal Ltd	ULREHMAN AL GOSAIBI	FSN	A/CA
New	Injection devices	8/25/2015	Vygon UK Ltd	el Medical & Trading Co.	FSN	A/CA
New	Magic3 Hydrophiliccoated Female Intermittent Catheter	8/30/2015	C.R. Bard, Inc.	Arabian Trade House Est.	2	http://ncmdr.sfda
New	Medfusion Stopcock	8/24/2015	Smiths Medical ASD Inc..	CARE DRUG STORE COM	FSN	A/CA

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Medtronic Passive Biopsy Needle Kit	8/30/2015	Medtronic Navigation Inc	Al Amin Medical Instruments Co. Ltd.	2	http://nc
New	Premicath + stylet + microflash intro	8/25/2015	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	FSN	http://nc

* The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI

*  Indicates that medical devices subject to removal and/ or destroyed action.

* SBED Team Recommend ensuring The listed Distributors in this report as they may differ from the distributors you are dealing with

SBED is devoted to receive the adverse event report and feedback information about any medical devices malfunction from hospitals and healthcare facilities all around KSA, studying them and collaborative working with manufacturers, authorized representatives and distributors to take the right action and assuring the proper safe performance.

To see recent recalls kindly visit the following link:

<http://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx>

In case you find an effected medical devices by any of the published FSN/Recalls, we urges you to contact the local representative and the National Center for Medical Device Reporting in order to ensure corrective or planed action been implemented.