



SBED Weekly Update 19-Aug-15

Dear,
SBED team is pleased to inform you that **74** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/10/2015 to 8/16/2015
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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Anaesthetic and respiratory devices

New	Fine Pressure Regulator	8/16/2015	Synthes Inc	Isam Economic Co.	FSN	A/Ca\
New	MicroGas 7650 Operator Manual used with Radiometer MicroGas 7650 Transcutaneous Monitor	8/13/2015	Radiometer Medical	Salehiya Trading Est.	2	http://nc.mdr.sfda
New	Siesta i TS machine	8/16/2015	Philips Burton	s Healthcare Saudi Arabi	2	A/Ca\

Assistive products for persons with disability

New	Back Table Cover supplied in a limited range of Operating Room Packs	8/13/2015	ITL Healthcare	N/A	2	http://nc.mdr
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Gazin Balls 2+3 and Gazin Balls 2+2	8/13/2015	Lohmann & Rauscher International	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	http://

Diagnostic and therapeutic radiation devices

New	ACUSON S Family Ultrasound Systems utilising the 18L6 HD and/or 6C1 HD biopsy guidelines	8/13/2015	Siemens Medical Solutions	Siemens Medical Solutions	2	http://ncmdr.sfda
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New	Acuson S2000 and Acuson S3000 Ultrasound Systems with the Virtual Touch IQ option	8/13/2015	SIEMENS	Siemens Medical Solutions	1	http://ncmdr
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New	AKITA JET and AKITA ² APIXNEB inhalation systems manufactured by Vectura GmbH	8/13/2015	Vectura GmbH	N/A	FSN	http://ncmdr
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New	Artis Q and Q.zen Floorstand and ArtisQ and Q.zen Biplane Floorstand systems with SW version VD10E	8/16/2015	Siemens Medical Solutions	Siemens Medical Solutions	2	http://ncmdr.sfda
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New	Artis systems with SW version VC14J	8/13/2015	SIEMENS	Siemens Medical Solutions	2	http://
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New	Centricity PACS IW with Universal Viewer Version 5.0 and Centricity Universal Viewer Version 6.0 products	8/12/2015	GE Healthcare	GE Healthcare	FSN	http://ncmdr.sfda
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New	MOSAIQ Release 2.41 and higher	8/13/2015	Elekta CMS Software	Analysis Device For Medical and Scientific	FSN	http://
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New	MR ACGD Cabinet FRU X Gradient Cable used with GE MRI System	8/16/2015	GE Healthcare	GE Healthcare	1	http://nc
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Update	RadiForce RX650, 6MP Color LCD Monitor	8/13/2015	Eizo Corporation	N/A	2	http:
New	TraumaDiagnost	8/16/2015	Philips Healthcare	s Healthcare Saudi Arabi	FSN	A/CaV
New	Tumor LOC software application on various GEMINI PET/CT System	8/16/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	http://nc

Electro mechanical medical devices

New	Activa® PC, Activa® SC, Activa® RC, Activa® PC+S, Kinetra®, and Soletra®	8/11/2015	Medtronic Inc	Gulf Medical Co.	FSN	http://ncmdr
New	Animas® Vibe Insulin Pump	8/16/2015	Animas Corporation .	Saudi Import Co. Banaja	FSN	http:
New	Battery Oscillator II, Handpiece	8/16/2015	Synthes Inc	Isam Economic Co.	FSN	http:
New	EnVeo R Loading System ..	8/10/2015	Medtronic Inc	Gulf Medical Co.	FSN	A/CaV
New	Lyra MP Reader II	8/11/2015	Bio Rad	Al Nahir Trading Co	FSN	A/CaV
New	mylife OmniPod Insulin Management System	8/11/2015	Insulet Corporation	Medical Technology Establishment	FSN	http:
New	Neria Infusion Administration Set	8/13/2015	Unomedical A/S	Analysis Device For Medical and Scientific	2	http:
New	PiCCO catheter	8/13/2015	Pulsion Medical Systems.	el Medical & Trading Co.	FSN	A/CaV
New	RFS wire fixation bolt slotted	8/12/2015	Ortho Solutions	N/A	FSN	http:
New	Rival PTA Dilatation Catheters	8/13/2015	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	FSN	http:

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Sapphire Infusion Pump ..	8/11/2015	Hospira Inc	AL-KAMAL Import	FSN	A/CA
New	Syramed μ SP6000 and Volumed μ VP7000 Special TCI Protocol Greenblatt Midazolam	8/11/2015	Arcomed AG	Al-Faisaliah Medical System	FSN	http://ncmdr

In vitro diagnostic devices

New	Neutral red 0.5% aqueous, Gram stain kit (neutral red counterstain) (RRSP109, RRSK5)	8/12/2015	Atom Scientific Limited	N/A	FSN	http://ncmdr
New	Access Thyroglobulin Reagent Kit For use with the Access Family of Immunoassay Systems	8/16/2015	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	http://ncmdr
New	BBL CHROMagar MRSA II	8/16/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	A/CA
New	BD CD56 PE-Cy7	8/10/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	A/CA
New	BD Vacutainer Eclipse Signal Blood Collection Needle with Integrated Holder 21G & 22G.	8/16/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	http://ncmdr
New	Cholesterol, CHOD-PAP, Cholesterol HDL Direct, immunoinhibition, Cholesterol LDL Direct, enzymatic selective protection, Creatinine, enzymatic, PAP, Glucose, GOD-PAP, NEFA, ACOD-PAP, Triglycerides, GPO-PAP, Uric Acid TBHBA, enzymatic colorimetric, Uric Ac	8/10/2015	DIALAB GmbH	Abdullah A. Baghaffar	FSN	http://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
New	CLINITEK Novus Analyzer	8/10/2015	Siemens Healthcare Diagnostics	Ibrahim Batterjee & Bros	FSN	A/CA

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New	DELFIAXpress PIGF Kit	8/16/2015	Immer Life and Analytical S	ULREHMAN AL GOSAIBI	2	A/CaV
New	Dimension Creatinine and Dimension Vista Creatinine Assays	8/16/2015	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	2	http://nc
New	Enzygnost Anti-HCV 4.0 on BEP 2000 / BEP 2000 Advance System	8/13/2015	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	http://nc
New	iChemVELOCITY Automated Urine Chemistry System using iChemVELOCITY Urine Chemistry Strips	8/16/2015	IRIS Diagnostics	Arabian Medical Marketing Co. (AMCO)	FSN	http://nc mdr sfda
New	InnovaStar values of GL Control N and P	8/13/2015	DiaSys Diagnostic Systems GmbH	N/A	FSN	http://
New	Insulin-like Growth Factor	8/13/2015	Unodiagnostic Systems Lir	Mais Co. For Medical Pro	1	A/CaV
New	Leica ASP200S & Leica ASP300S.	8/16/2015	Leica Microsystems Inc.	Al-Faisaliah Medical System	2	http://
New	MicroScan LabPro Information Manager System	8/16/2015	Beckman Coulter Inc	El Seif Company	1	http://nc
New	RAPIDPoint® 500 System	8/16/2015	Siemens Healthcare Diagnos	Ibrahim Batterjee & Bros	FSN	A/CaV
New	Sterile Water for Irrigation, 1000mL & 0.9% Sodium Chloride for Irrigation	8/16/2015	Baxter Healthcare	Baxter AG	FSN	http://nc mdr
New	UniCel DxC ISE Reference reagent tubing	8/16/2015	Beckman Coulter Inc	El Seif Company	2	http://
New	VITROS 5,1 FS System	8/13/2015	Ortho-Clinical Diagnostics	Photographic Supplies C	2	A/CaV

Medical software

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	IntelePACS software versions from 4.5.1 to 4.11.1.	8/16/2015	Intelrad Medical Systems Inc.	bio standards	2	http://nc

Non-active implantable devices

New	200 mm sinus-SuperFlex-635 self-expanding nitinol stent system	8/13/2015	OptiMed Medizinische Instrumente GmbH	Syts Trading Est.	FSN	http://nc
New	ATTUNE® INTUITION™ tibial articulation surface instrument.	8/12/2015	DePuySynthes	Isam Economic Co.	FSN	http://nc
New	DePuy Synthes Socket, Hexagonal Ø 4.0mm/11.0mm.	8/16/2015	DePuySynthes	Isam Economic Co.	2	http://nc
New	Direct Flow Medical Transcatheter Aortic Valve System	8/16/2015	Direct Flow Medical	N/A	FSN	http://nc
New	E-tegra Stent Graft System	8/16/2015	Jotec GmbH..	First Medical co. Ltd.	FSN	A/CaV
New	Mitroflow Model 12, LXA and DL	8/13/2015	Sorin Group	Arabian Trade House Est.	FSN	http://nc
New	OptiSplint Endoprosthesis	8/13/2015	Medizinische Instrument	Syts Trading Est.	FSN	A/CaV
New	Oscillating Saw Attachment for Colibri / Colibri II / Small Electric Drive	8/16/2015	Synthes Inc	Isam Economic Co.	FSN	http://nc mdr.
New	Polymaille Extra Thin vascular prosthesis	8/12/2015	Perouse Medical	N/A	FSN	http://nc
Update	Stryker Sterile Implants	8/16/2015	Stryker Instruments	I-Faisaliah Medical System	2	A/CaV
New	Sureshot Humeral 3.2mm AO Drill	8/13/2015	Smith & Nephew inc	Smith & Nephew inc	2	http://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Talux, Vari-Flex, Vari-Flex XC, Re-Flex Shock, Re-Flex Rotate, Flex-Foot Assure, Balance Foot J	8/10/2015	Ossur	Al Ewan Medical Company	FSN	http://nc.mdr
New	Triathlon Inserts, Triathlon X3 PS Tibial Insert #5 11mm, Triathlon X3 TS Plus Tibial Insert #3 19mm	8/13/2015	Stryker Orthopaedics	Al-Faisaliah Medical System	FSN	http://nc.mdr.sFDA
New	Vertical Expandable Prosthetic Titanium Rib (VEPTR)	8/16/2015	Synthes Inc	Isam Economic Co.	1	http://nc
New	Waratah Private General Packs and Waratah Private Knee/Shoulder Arthro Pack	8/16/2015	Molnlycke Health Care AB	FAROUK, MAAMOUN TAMER & COMPANY	2	http://nc.mdr

Ophthalmic and optical devices

New	Silicone Oil Syringe	8/16/2015	Ophthalmic Research Center	First Gulf Co.	FSN	A/Ca
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Reusable devices

New	Magic Hydrophilic-coated Female Intermittent Catheter products	8/13/2015	Rochester Medical Corp	Salehiya Trading Est.	FSN	http://nc.mdr
New	Stryker SelectCore Variable Throw Biopsy Device, 14G, 10CM	8/16/2015	Stryker Communications	Al-Faisaliah Medical System	2	http://nc

Single-use devices

New	20 ml Vygon Nutrisafe C-GON Enteral syringes code 1015.202	8/16/2015	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	FSN	http://nc
New	ARROW® International PICC Kits with Peel-Away Sheath Component	8/12/2015	Arrow International Inc	Gulf Medical Co.	FSN	http://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Fannin Integral Silicone Laryngeal Mask - standard size 2 (single use)	8/16/2015	INTEGRAL MEDICAL PRODUCTS CO., LTD	JAMJOOM MEDICAL INDUSTRIES CO. LTD.	FSN	http://ncmdr
New	Mölnlycke Health Care ProcedurePak, single-use	8/16/2015	Mölnlycke Health Care AB	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http://ncmdr
New	Nit-Occlud Implantation Sheath	8/11/2015	pfm medical ag	United Medical Group	FSN	http://ncmdr
New	Perfectum Tuberculin Glass Syringe & Micro-Mate Tuberculin Glass Syringe	8/13/2015	Cadence Science, Inc	N/A	FSN	http://ncmdr
New	Wrap f/ Medullary Nails	8/16/2015	Synthes Inc	Isam Economic Co.	1	A/CaV
New	Y connector code 884.08	8/16/2015	Vygon UK Ltd	el Medical & Trading Co.	FSN	A/CaV

- * 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.