



SBED Weekly Update 08-May-17

Dear,

SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/2/2017 to 5/7/2017
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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Assistive products for persons with disability

New	Omega Incline Platform Lift	5/7/2017	Savaria Concord Lifts, Inc.	N/A	2	https://nc
New	Sonesta S2	5/7/2017	Sonesta Medical	Gulf Medical Co.	2	A/Ca

Diagnostic and therapeutic radiation devices

New	DigitalDiagnost 3.1.x	5/4/2017	Philips Healthcare	s Healthcare Saudi Arabia	FSN	A/Ca
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Electro mechanical medical devices

New	neoBLUE LED Phototherapy Lights (2nd Generation)	5/7/2017	Natus Medical Inc.	Saudi Health Services Co. Ltd.	2	https://nc.mdr
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New	Philips IntelliVue Neuromuscular Transmission Patient Cable	5/7/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc.mdr.sfda
Update	Valleylab Laparoscopic Handset, Four-Function	5/4/2017	Covidien LLC	Covidien AG	1	https://nc
Update	ViperWire Advance Peripheral Guide Wire with Flex Tip	5/3/2017	Cardiovascular Systems, Inc	N/A	2	https://nc.mdr

In vitro diagnostic devices

New	Access BR Monitor used with the Access Family of Immunoassay Systems	5/4/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr
New	BD Viper LT software, version 3.00H	5/3/2017	BD Diagnostic Systems	Becton Dickinson B.V.	2	https://nc
New	Blood Agar (TSA with 5 Sheep Blood)	5/7/2017	Remel	AL-MOHANAD MEDICAL EST	2	https://nc
New	eMAG nucleic acid extraction system	5/3/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
New	IMMULITE®/IMMULITE® 1000 Lipopolysaccharide Binding Protein (LBP)	5/3/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	https://nc.mdr
New	LIAISON® Control Borrelia IgM Quant / Borrelia IgM II	5/2/2017	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	FSN	https://nc.mdr
New	Shandon Rapid Chrome KwikDiff	5/7/2017	Richard-Allan Scientific	Fuad Abdul Jalil Al Fadhli & Sons	2	https://nc
New	Stratus® CS Acute Care™ CCRP TestPak	5/3/2017	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	TruCal HbA1c liquid	5/3/2017	ys Diagnostic Systems Gm	N/A	FSN	A/Ca\
New	VITEK 2 Identification / Antimicrobial Susceptibility Test Cards.	5/7/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://ncmdr.

Laboratory equipment

New	Vacutainer Tubes	5/3/2017	Avid Medical, Inc.	N/A	2	A/Ca\
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Non-active implantable devices

New	Guide Wires	5/7/2017	Amendia, Inc	N/A	2	A/Ca\
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New	Fortex Pedicle Screw System	5/7/2017	XTANT MEDICAL INC	N/A	2	https://ncmdr.
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New	Navitrack System OS Knee Universal	5/7/2017	Orthosoft, Inc	N/A	2	https://ncmdr.
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New	Safety Clip - Hoffmann Limb Reconstruction Frame (LRF) Bone Transport	5/7/2017	Stryker Europe	Al-Faisaliah Medical System	2	https://ncmdr.sfda.
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New	SmartTools Knee System	5/3/2017	Zimmer Biomet	n Medical Instruments Co	2	A/Ca\
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New	uNion CPS	5/7/2017	Ulrich GmbH & Co. KG	Isam Economic Co.	2	A/Ca\
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Ophthalmic and optical devices


New	Laser photocoagulator Easyret	5/7/2017	Quantel Medical	First Gulf Co.	1	https://ncmdr.
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New	Vitrectomy Cutter ,	5/7/2017	Abbott Medical Optics Inc	Gulf Medical Co.	2	A/Ca\
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Single-use devices

New	Arrow gard Blue PLUS Central Venous Catheter	5/3/2017	Arrow International Inc	Gulf Medical Co.	2	https://ncmdr.
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Packaged Kits	5/3/2017	Alcon Research, Ltd	n Medical Instruments Co	2	A/Cal
New	Venture RX, OTW and CS Catheters	5/7/2017	Vascular Solutions Inc	Medical Technology Establishment	2	https://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.