



SBED Weekly Update 20-Mar-17

Dear,
SBED team is pleased to inform you that **27** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 3/13/2017 to 3/19/2017
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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Anaesthetic and respiratory devices

New	Vivano Med Abdominal Kits	3/16/2017	PAUL HARTMANN	ABDULREHMAN AL GOSAIBI GTB	FSN	https
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Dental devices

New	RTI Biologics BioSet IC RT Paste 2 cc	3/14/2017	RTI Surgical, Inc ,	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https
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New	Sealapex Xpress	3/15/2017	Kerr Corporation	MAAMOUN TAMER & C	2	A/CaV
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Diagnostic and therapeutic radiation devices

New	Allura Xper X-ray Systems ,	3/19/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https
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New	BrightView, BrightView X and BrightView XCT with Tangential, Radius, and Roll drive assembly .	3/13/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	1	https://ncmdr
New	MDRC-1119 display	3/19/2017	Barco	Medical regulations gate	FSN	A/Ca
New	ORBITARIS handle	3/16/2017	Bissinger Medizintechnik	MAAMOUN TAMER & C	FSN	A/Ca
New	PRIMUS HI, MEVATRON	3/14/2017	Siemens Medical Solutions	Siemens Medical Solution	2	A/Ca
New	Wireless Foot Switch utilised on Artis systems	3/15/2017	SIEMENS	Siemens Medical Solutions	2	https

Electro mechanical medical devices

New	CADD Solis VIP	3/14/2017	Smiths Medical ASD Inc..	CARE DRUG STORE COM	2	A/Ca
New	MiniMed 640G Insulin Infusion Pump	3/16/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https

In vitro diagnostic devices

New	ADVIA Chemistry Enzyme 2 Calibrator	3/19/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https
New	Alere Afinion Lipid Panel Control	3/19/2017	Alere.	Waleed Al-Madani Est.	FSN	https
New	Capture-R Ready-ID	3/19/2017	Immucor GmbH.	Supplies & Services Co.Ltd	FSN	A/Ca
New	i-STAT1 Analyzer Software , i-STAT Celite ACT cartridges and i-STAT Kaolin ACT Cartridges	3/19/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https://ncmdr.sfda.gov.s
New	Liaison C-Peptid Assay	3/15/2017	DiaSorin Inc	LA FOUAD HOLDING CO	2	A/Ca

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New	Panocell-20 .	3/19/2017	Immucor GmbH.	Supplies & Services Co.Ltd	FSN	A/Ca


Non-active implantable devices

New	Bencox Mirabo PE Liner 36/44	3/14/2017	CORENTEC CO., LTD	N/A	2	https
New	Inion Hexalon, Inion Trinion and Inion GTR Tacks	3/19/2017	Inion Oy	Bio Standards	FSN	https://nc
New	PANTA / XL nails	3/16/2017	Integra LifeSciences	Bio Standards	FSN	A/Ca
Update	RSP and Turon Impaction Fixtures	3/19/2017	Encore Medical, Lp	Al Ewan Medical Company	2	https
New	Verticale pedicle / iliac screws dia. 8.2 / 9.2 / 10.2 mm	3/16/2017	Silony Medical	N/A	FSN	https://nc

Single-use devices

New	Cook Bush SL and Bush DL Ureteral Illuminating Catheters	3/15/2017	William Cook Europe ApS	NAFA Medical	2	https://nc
New	Curity™ Eye Pad Oval and Curity™ Sodium Chloride Dressing	3/19/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
New	Disposable Kits for Patient Positioning	3/19/2017	Smith & Nephew	Alhaya medical co.	FSN	https
New	Secondary Sets containing Back Check Valve	3/19/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	FSN	https://nc
New	Thoracentesis/paracentesis kit, Illinois needle aspiration, Jamshidi needle bone marrow	3/15/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	2	https://nc mdr.

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- * 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.