



SBED Weekly Update 12-Aug-15

Dear,
SBED team is pleased to inform you that **22** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/3/2015 to 8/6/2015
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	Puritan Bennett™ 980 Series Ventilator System For Universal and Neonatal Models	8/5/2015	Covidien LLC	Covidien AG	FSN	http://nc.mdr
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Assistive products for persons with disability

New	Relax wall mounted shower seat	8/6/2015	Etac	Medicare Center	FSN	http://nc.mdr
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Diagnostic and therapeutic radiation devices

New	ACUSON S1000, ACUSON S2000, or ACUSON S3000 ultrasound systems	8/5/2015	Siemens Medical Solutions	Siemens Medical Solutions	FSN	http://nc.mdr
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Update	Allura systems. Actuator Monitor Ceiling Suspension (MCS)	8/5/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	http://nc	
New	E.CAM	8/6/2015	Siemens Medical Solutions	Siemens Medical Solution	FSN	A/CA	
New	Efficia DFM100 Defibrillator/Monitors	8/6/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	http://nc	
#	New	Head Holders Shipped with Ingenuity Core Computed Tomography Systems	8/3/2015	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	2	UCA
New	iPlan RT Dose	8/5/2015	BrainLAB	el Medical & Trading Co.	FSN	A/CA	
#	New	Various Aquilion CT Scanners	8/3/2015	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	

In vitro diagnostic devices

New	BD BBL Vancomycin Screen Agar	8/6/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	http://nc
New	Cholesterol FS, Creatinine PAP FS, Glucose GOD FS, Glucose/Hemoglobin IS, HDL-C Immuno FS, LDL-C Select FS, NEFA FS, Phospholipids FS, Triglycerides FS, Uric acid FS TBHBA, Uric acid FS TOOS	8/6/2015	DiaSys Diagnostic Systems GmbH	N/A	FSN	http://nc.mdr.sfda.gov.sa/Secure/CA/C
New	Oxoid MacConkey Agar No. 3	8/6/2015	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	1	http://nc
New	Reflotron Uric Acid	8/5/2015	Roche Diagnostics Ltd	MAAMOUN TAMER & C	FSN	A/CA
Update	STERRAD Cassettes..	8/5/2015	Advanced Sterilization Products	MAAMOUN TAMER & C	FSN	A/CA


Non-active implantable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Assy, 2mm and 4mm Offset Femoral Alignment Locating Guide Revision Femur	8/4/2015	OMNIlife science	N/A	FSN	http://nc.mdr
New	ATTUNE INTUITION Tibial Articulation Surface Instruments	8/4/2015	Depuy Orthopaedics	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http://nc
New	M-Biopsy Coaxial Introducer Needle	8/4/2015	Mermaid Medical	N/A	FSN	http:

Single-use devices

#	New	9100 Series Cholangiogram Catheters	8/3/2015	American Diagnostica Inc	N/A	2	
	New	Beacon Tip Torcon NB Advantage Catheters, Beacon Tip Royal Flush Plus High-Flow Catheters, Slip-Cath Beacon Tip Catheters	8/6/2015	Cook Inc,	NAFA Medical	FSN	http://nc.mdr.sfda.gov.s
#	New	Pioneer Plus Intravascular Ultrasound Guided Re-Entry Catheters	8/3/2015	Volcano Corp	Alhaya medical co.	2	
#	New	Various Elcam Stopcock and Manifold Products	8/3/2015	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	
#	New	Vascular Loops	8/4/2015	CareFusion Corp	Arabian Trade House Est.	2	

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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.