



SBED Weekly Update

08-Oct-15

Dear,

SBED team is pleased to inform you that **40** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 9/28/2015 to 10/4/2015
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	Armstrong Medical vented tracheal tube introducer with oxygen connector	9/29/2015	P3 Medical Ltd	Medical Oasis International	FSN	http://nc.mdr
New	Arkon anesthesia delivery system	10/4/2015	Spacelabs Healthcare Inc	Gulf Medical Co.	FSN	http://

Assistive products for persons with disability

New	NRS 4 Wheel rollators	10/4/2015	NRS Healthcare	N/A	FSN	A/Cal
New	Prism Medical P300 and C300 Ceiling Hoist	10/4/2015	Rehab Assist Pty Ltd	N/A	2	http://
New	Shuttle Discovery	9/29/2015	tedifab Medical Fabricatio	N/A	FSN	A/Cal

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Diagnostic and therapeutic radiation devices

#	Update	Allura systems. Actuator Monitor Ceiling Suspension (MCS)	9/30/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	
	Update	AXIOM Artis X-ray Systems.	10/4/2015	SIEMENS	Siemens Medical Solutions	2	http:
	New	Telemis-Medical image viewing software	10/2/2015	Telemis S.A.	N/A	FSN	http:

Electro mechanical medical devices

#	New	ACCU-CHEK Inform II Systems..	9/30/2015	Roche Diagnostics Corp	Roche Diagnostics Corp	2	
#	New	CADD-Solis Ambulatory Infusion Pumps	9/30/2015	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	
	New	Giraffe Shuttle Products	10/4/2015	GE Healthcare	GE Healthcare	2	A/CaV
	New	KleenSpec Corded illumination System	10/2/2015	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	FSN	http:
	New	MiniMed 640G insulin pump	10/4/2015	Medtronic Diabetes	Salehiya Trading Est.	2	http:
#	Update	mylife OmniPod Insulin Management System	9/29/2015	Insulet Corporation.	N/A	FSN	
	New	Philips GoSafe Mobile Help Button; 7000MHB	10/4/2015	Lifeline Systems, Incorporated	Philips Healthcare Saudi Arabia Ltd.	2	http:

Hospital hardware

	New	SCALEO Medical spreader bar for MOLIFT Air or HITRAC ceiling hoists	10/2/2015	SCALEO MEDICAL	N/A	FSN	http://nc
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In vitro diagnostic devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c) used on the ADVIA 1200, 1650, 1800, 2400, and XPT Chemistry Systems	9/29/2015	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	2	http://nc.mdr.sfda.gov.s
New	chemistry premium plus control	10/4/2015	Randox Laboratories Ltd	Alinfrad Trading Est.	FSN	http://
#	Dimension PHOS Reagents	9/28/2015	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
New	INSTI HIV-1/HIV-2 antibody test kit	10/4/2015	BioLytical Laboratories	N/A	FSN	http://
#	MICroSTREP plus 1 and MICroSTREP plus 2 Panels	9/28/2015	Beckman Coulter, Inc..	ABDULREHMAN AL GOSAIBI GTB	2	
New	tests based on trinder reactions	10/4/2015	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	FSN	http://
New	VITROS Chemistry Products Calibrator Kit 9	10/4/2015	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	1	http://

Medical software

#	New	DiversiLab Software	9/29/2015	bioMerieux Inc	Al-Jeel Medical	2	
New	Patient Data Manager, Origin Data Management	10/4/2015	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	FSN	http://	

Non-active implantable devices

New	MOSAICPLASTY DP – disposable harvesting system	9/29/2015	Smith & Nephew	Zimmo Trading Establishment.	FSN	http://nc	
#	New	Duracon Augments	9/28/2015	Stryker Howmedica	Zimmo Trading	2	

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New	Endolite dynamic pylon top housing	9/29/2015	Blatchford Products Ltd	N/A	FSN	http:
New	Exeter Small and Large Tapered Pin Reamer	10/4/2015	Stryker Instruments.	Zimmo Trading Establishment.	2	http:
New	PCA Tapers, LFIT V40 Tapers, V40 Tapers	10/4/2015	Stryker Howmedica Osteonics Corp	Zimmo Trading Establishment.	2	http:
# New	Specialist 2 Intramedullary Rod 400 mm Instruments	9/28/2015	DePuySynthes	Isam Economic Co.	2	
# New	Various Medical Devices..	9/28/2015	Silimed Inc	N/A	2	

Ophthalmic and optical devices

New	REFRESH NIGHT TIME and Ircal Eye Ointments	10/2/2015	Allergan Medical SA	Al-Nozha Medical Est	2	http:
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Single-use devices

# New	100 mL 0.9% Sodium Chloride Injections in MINI-BAG VIAFLEX Plastic Containers	9/29/2015	Baxter Corp Canada	Baxter AG	2	
New	BD Plastipak Syringes / BD Oral Syringes	10/4/2015	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	http:
New	forceps	10/4/2015	Single Use Surgical (SUS)	Hammad Medical Servic	FSN	A/Ca
New	Laryngeal Suction Tube with Soft Tip	9/29/2015	Pennine Healthcare	MEDICARE DRUG STORE COMPANY	1	http:
New	Reprocessed Zimmer Tourniquet Cuffs	9/30/2015	STERILMED, INC	N/A	2	http:
Update	Vented Tracheal Tube Guides (Bougies)	9/29/2015	P3 Medical Ltd.	Alwan Alnoor Trading Est.	1	http:

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Vented Tracheal Tube Guides (Bougies)	9/29/2015	P3 Medical Ltd.	Alwan Alnoor Trading Est.	1	http:

* 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.