



SBED Weekly Update

10-Apr-18

Dear,

SBED team is pleased to inform you that **37** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 4/2/2018 to 4/8/2018
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	Kinmed Aerosol Mask	4/8/2018	Kinmed Import & Export	Salehiya Trading Est.	FSN	A/Cal
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Assistive products for persons with disability

#	New	Lithium Ion Batteries in DynaVox T10 Speech Devices .	4/3/2018	Tobii Technology AB	N/A	2	Attac hed
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Biologically-derived devices


New	SporAmpule Biological Indicator	4/3/2018	Mesa Laboratories, Inc.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https
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Diagnostic and therapeutic radiation devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Discovery IGS 730/740, Innova IGS 620/630/520/530/540 systems	4/8/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr
Update	Monica IF24 Interface Systems	4/4/2018	GE Healthcare	GE Healthcare	FSN	https
# Update	MYLAB TWICE EHD	4/4/2018	Esaote S.p.A.	Salehiya Trading Est.	FSN	ttache 
# New	Proteus 235 Proton Therapy Systems ,	4/2/2018	Ion Beam Applications S.A.	N/A	2	https
New	Syngo.via.	4/8/2018	Siemens Medical Solutions	Siemens Medical Solution	2	A/Ca

Electro mechanical medical devices

New	2008 Series Hemodialysis Machine	4/3/2018	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	https
New	6F Taiga Guiding Catheter	4/3/2018	Medtronic SA	Medtronic Saudi Arabia	1	A/Ca
New	8F Plastic Dignity Low Profile CT Port	4/3/2018	Medical Components, Inc	Farabi Trading Establishment	2	https
New	Alpha Air 6 ENT Microscope	4/4/2018	Seiler Instrument & Manufacturing Inc, Co	Samir Trading and Marketing CJSC.	2	https
# New	Infinity Acute Care Systems and Standalone Infinity M540 Patient Monitors .	4/4/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	2	Attac hed 
# Update	Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor ,	4/5/2018	Radiometer America Inc	Salehiya Trading Est.	1	Attac hed 
New	Sarns TCM and TCM II Cooling and Heating Systems	4/4/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	T34 Ambulatory Syringe Pumps .	4/5/2018	Caesarea Medical Electronics Ltd	N/A	2	Attac 
#	New	Xper Flex Cardio Patient Monitoring Systems .	4/2/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attac 
In vitro diagnostic devices							
#	Update	ACCU-CHEK Inform II Blood Glucose Meters	4/5/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac 
#	Update	Automate 1250 and 2550 Sample Processing Systems ,	4/5/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	Attac hed 
#	New	cobas z 480 0.3 mL AD-Plates	4/4/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac 
	New	cobas® 8000 modular analyzer series & cobas e 801 module	4/8/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc
#	Update	Foetal Haemoglobin Monoclonal Antibody (HbF-1), FITC	4/4/2018	Life Technologies Limited.	Integrated Gulfbiosystems	2	Attac hed 
#	New	Iris iChemVELOCITY Automated Urine Chemistry Systems .	4/3/2018	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	Attac hed 
	New	LeadCare Plus and LeadCare II Blood Lead Analyzer	4/8/2018	Magellan Diagnostics Inc	N/A	2	https://nc
	New	oneHbA1c FS .	4/8/2018	ys Diagnostic Systems Gr	ALGhuyum Scientific Tradir	FSN	A/Ca\
	Update	oneHbA1c IS INNOVASTAR	4/5/2018	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Vacutainer Plus SST Blood Collection Tubes with Hemogard Closure .	4/3/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	Attac hed 


Non-active implantable devices

New	A.L.P.S. MinimallyInvasive (MIS) and Mesh Calcaneus Plating System	4/8/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
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New	Retractor f/Sciatic Nerve & Retractor f/Sciatic Nerve long .	4/8/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	FSN	https://nc
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Ophthalmic and optical devices


New	FEMTO LDV(TM)Z8 Femtosecond Surgical Laser	4/3/2018	SIE AG, Surgical Instrument Engineering	Medicals International Saudi Arabia for Maintenance & Repair	2	https://nc
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#	New	Sterile Eye Droppers	4/2/2018	Torbay Pharmaceuticals	N/A	2	ttache 
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Reusable devices


#	New	Prestige LP Cervical Disc Streamlined Instruments .	4/3/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed 
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Single-use devices

#	New	MicronDevices Syringes and Caps Contained in Sterile Medical Packs	4/5/2018	Micronclean	N/A	2	Attac hed 
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#	New	Vacutainer Push-Button Blood Collection Sets ,	4/5/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	Attac 
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#	New	Various Bandage Products .	4/5/2018	Johnson & Johnson Medical GmbH.	Ahmed Mohammed Abdulwahab Naghi &	2	Attac 
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#	New	Various Operating Room Products .	4/4/2018	Synergy Health	Ever Health Trading Est.	2	Attac 
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	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	ZNN & M/DN Guidewires ,	4/5/2018	Zimmer Inc.....	Isam Economic Co.	2	Attac

- * 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.