



SBED Weekly Update 29-Aug-17

Dear,
SBED team is pleased to inform you that **39** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/21/2017 to 8/27/2017
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
-----------	---------------	-----------	--------------	------------	-------	------

Anaesthetic and respiratory devices

New	HAMILTON-C3, HAMILTON-C2 ventilator units	8/25/2017	Hamilton Medical Inc	Taleiamedical	FSN	https://nc
-----	---	-----------	----------------------	---------------	-----	-------------------------------------

# New	UniPerc Adjustable Flange Tracheostomy Tube Kits	8/21/2017	Smiths Medical International Limited	almadar medical Est.	2	Attac hed
-------	--	-----------	---	----------------------	---	-------------------------------

Complementary therapy devices

Update	VASER Amplifiers	8/24/2017	Solta Medical	ALTRA GLOBAL TRADING	2	A/Cal
--------	------------------	-----------	---------------	----------------------	---	-----------------------

Diagnostic and therapeutic radiation devices

New	Allura Xper R9 and Azurion R1.1	8/24/2017	Philips Healthcare Gamma Cameras	Philips Healthcare Saudi Arabia Ltd.	FSN	https
-----	------------------------------------	-----------	-------------------------------------	---	-----	---------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	TrueBeam and VitalBeam Radiotherapy Systems and EDGE Radiosurgery Systems	8/21/2017	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	2	Attached
# New	Various FDR/CR Digital Mammography Systems	8/21/2017	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac
Update	Various FDR/CR Digital Mammography Systems	8/25/2017	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	2	https

Electro mechanical medical devices

New	Defibrillation Electrode SKINTACT DF59N Defibrillation Electrode SKINTACT DF59NC	8/21/2017	Leonhard Lang GmbH	Teriag International	FSN	https://nc.mdr
-----	---	-----------	--------------------	----------------------	-----	---

Healthcare facility products and adaptations

# New	Multi-Movement Imaging Tables	8/21/2017	Oakworks	N/A	2	Attac
# Update	Multi-Movement Imaging Tables	8/21/2017	Oakworks	N/A	2	Attac

In vitro diagnostic devices

New	Abbott RealTime HIV-1 Qualitative Amplification Reagent Kit	8/27/2017	Abbott Molecular Inc Sub Abbott Laboratories	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc
New	ADVIA Centaur XPT T3	8/21/2017	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/Ca\
Update	ADVIA Centaur XPT T3	8/25/2017	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/Ca\
New	BD MultiTEST CD3/CD8/CD45/CD4	8/21/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	https
New	Bioscot Anti-Fyb monoclonal human IgM	8/21/2017	Millipore Corporation.	DAR ALAALMIYAH TRADING EST	FSN	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
Update	cobas 8000 core unit	8/24/2017	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	A/Cal
Update	cobas e 601, cobas e 602 MODULAR Analytics	8/24/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https
New	Immunoassay Premium and Premium Plus Quality Controls	8/21/2017	Randox Laboratories Ltd.	Bio Standards	FSN	https://nc
New	Liquid Cardiac Control Level 3	8/21/2017	Randox Laboratories Ltd.	Bio Standards	FSN	https
# New	Phadia AB ImmunoCAP Herring Allergens	8/21/2017	ThermoFisher.	ABDULREHMAN AL GOSAIBI GTB	2	https
New	VITEK 2 Compact 15 and 30	8/27/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https
New	VITEK 2 Gram-Positive (GP) Identification (ID) Test Kit	8/25/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc

Laboratory equipment

New	Convertors Robotic Drape with Attached Leggings; Product is packaged as Single Sterile Drape	8/24/2017	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	https://nc.mdr.sfda
# New	ICU Medical Blood Sets	8/21/2017	Medline Industries Inc...	Ikar Establishment	2	ttache

Non-active implantable devices

New	FemoSeal Vascular Closure System	8/21/2017	TerumoBCT	ABDULREHMAN AL GOSAIBI GTB	FSN	https
New	OPT Croutons synthetic bone substitute	8/24/2017	Acumed LLC	N/A	2	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	PALACOS and COPAL bone cements	8/25/2017	Heraeus Medical GmbH	Al Amin Medical Instruments Co. Ltd.	FSN	https
New	Various custom surgical kits	8/24/2017	Custom Assemblies Inc	N/A	2	https
# New	Various Hip Products	8/21/2017	er Howmedica Osteonics	hmo Trading Establishme	2	ttache

Ophthalmic and optical devices

New	ORA System with VerifEye	8/24/2017	Alcon Research, Ltd	in Medical Instruments C	2	A/Cal
-----	--------------------------	-----------	---------------------	--------------------------	---	---------------------------

Reusable devices

New	2.0MM QFx SCREW REMOVAL DRIVER	8/21/2017	Smith & Nephew inc	Smith & Nephew inc	FSN	https
New	LCP Drill Sleeve 1.5 f/Drill Bit diameter 1.1mm	8/21/2017	Synthes Inc	Isam Economic Co.	FSN	https
New	Saugerventil O.P.S	8/21/2017	IMT Medizintechnik GmbH	N/A	FSN	A/Cal

Single-use devices

# Update	AbbVie PEG, PEG Kit 15FR, 20FR	8/21/2017	AbbVie Inc..	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac
New	CADD(R) Medication Cassette with clamp and female Luer	8/27/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	https://nc
New	ENFit(R) AMERITUS NG FEEDING TUBE	8/27/2017	Kentec Medical Inc	N/A	2	https
# Update	MAX Vaginal Panels and UVE Specimen Collection Kits	8/21/2017	BD Biosciences	Becton Dickinson B.V.	2	Attac hed
Update	MAX Vaginal Panels and UVE Specimen Collection Kits	8/27/2017	BD Biosciences	Becton Dickinson B.V.	2	https://nc

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Novosyn Quick Undyed Sterile Absorbable Surgical Sutures	8/21/2017	B Braun Surgical SA	Gulf Medical Co.	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.