



SBED Weekly Update 16-Jan-18

Dear,
SBED team is pleased to inform you that **35** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 1/9/2018 to 1/15/2018
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
-----------	---------------	-----------	--------------	------------	-------	------

Anaesthetic and respiratory devices

New	Oxygen Cannulas ,	1/10/2018	Salter Labs..	yasmin albilali trading est	2	A/CaV
New	UNIVERSAL FLEX2 BREATHING CIRCUIT	1/9/2018	King Systems Corp. dba Ambu, Inc.	N/A	2	https


Complementary therapy devices

New	Sundream 12 V tanning bed	1/9/2018	ProSun International, LLC	N/A	2	https
-----	---------------------------	----------	---------------------------	-----	---	-----------------------


Dental devices

New	SwishTapered and SwishPlus Implant	1/15/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	FSN	https
-----	------------------------------------	-----------	---	---	-----	-----------------------


Diagnostic and therapeutic radiation devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	AXIOM Artis.	1/11/2018	SIEMENS	iemens Medical Solution	FSN	A/Cal
New	OrthoScan Mobile DI Mini Carm, OrthoScan Mobile DI Mini Carm, HD (10000001), HD (10000004)	1/14/2018	OrthoScan, Inc.	Saudi Health Services Co. Ltd.	2	https://nc.mdr.sfda
New	Philips IntelliVue Information Center (PIIC) iX .	1/11/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc
# New	Various Artis and Axiom Systems ,	1/15/2018	SIEMENS	Siemens Medical Solutions	2	



Electro mechanical medical devices

New	CARESCAPE Central Station (CSCS) ,	1/10/2018	GE Healthcare	GE Healthcare	FSN	https
New	Foot Control S-N1 / S-N2	1/9/2018	H Dentalwerk Bürmoos Gr	urki Medical Group Ltd (A	FSN	A/Cal
New	Freedom 60 Precision Flow Rate Tubing Sets	1/9/2018	Repro-Med Systems, Inc	N/A	2	https
# New	Medfusion 3500 and 4000 Syringe Infusion Pumps ,	1/15/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	

Hospital hardware

# New	OptiPro Multi-Enzymatic Low-Foaming Detergent	1/15/2018	Ecolab Deutschland GmbH	Salehiya Trading Est.	2	
-------	---	-----------	-------------------------	-----------------------	---	---

In vitro diagnostic devices

# New	13 mm Sample Tubes ,	1/9/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	2	
# New	Access 2 and UniCel DxC 600i SYNCHRON Access Clinical Systems	1/15/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	COBAS INTEGRA 400 plus/800/800 CTS Analyzers and MODULAR ANALYTICS P Modules	1/15/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	
	New	FlexLab, Accelerator a3600, Aptio Automation..	1/9/2018	Inpeco S.A.	Medical supplies & Services Co.Ltd	FSN	https
	New	Synchron Enzyme Validator	1/15/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	https
	New	VIDAS and mini VIDAS	1/15/2018	bioMerieux Inc	el Medical & Trading Co	FSN	A/CaV

Non-active implantable devices

	New	Ceres SelfDrilling Variable Screw 4.0 x 12mm	1/9/2018	Amendia, Inc	N/A	2	https
	Update	Cordis S.M.A.R.T.® Flex Vascular Stent System.	1/14/2018	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https
	New	DeRoyal Sterile Custom kits,	1/15/2018	DeRoyal Industries Inc.	Alhaya medical co.	2	https
	New	EMPOWR Porous Knee System TIBIAL PUNCH, LARGE, MEDIUM and SMALL	1/14/2018	Encore Medical, Lp	AL EWAN MEDICAL COMPANY	2	https://nc.mdr
	New	Mac Pin NonCannulated Screw	1/14/2018	Amendia, Inc	N/A	2	https
	New	Multiple Tibial Implants ,	1/15/2018	Tornier Inc	N/A	2	A/CaV
	New	NAJA Spinal Ligament Systems for Spinal Stabilization	1/15/2018	COUSIN BIOTECH	Al Amin Medical Instruments Co. Ltd.	2	https://nc
	New	RingLoc Acetabular Shells	1/9/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/CaV

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Synvisc-One Injections ,	1/15/2018	Genzyme Corporation	Arabian Trade House Est.	2	
New	TRISTANflex - Anterior Cervical Interbody Fusion	1/11/2018	Humantech Germany GmbH	Frdawous El Hekma Medical Co.	FSN	https://nc
New	TRYPTIK(R) 2 CPLATE SELFTAPPING POLYAXIAL SCREW	1/15/2018	SPINEART	Tina Medix Technologies Int. Co.	2	https://nc

Reusable devices

New	VOLISTA	1/15/2018	MAQUET Inc	Gulf Medical Co.	FSN	A/CA
-----	---------	-----------	------------	------------------	-----	-------------------------

Single-use devices

# New	4 Fr Dual Lumen and 3 Fr Single Lumen PowerPICC Catheters	1/15/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	
New	Bag for UV treatment of blood cells	1/9/2018	Macopharma SAS	Dar ALKarmel	FSN	https
New	Bulkamid VUR	1/15/2018	Contura International A/S	N/A	FSN	A/CA
# New	Perfusion Tubing Packs Containing Terumo Over-Pressure Safety Valves	1/15/2018	Medtronic SA	Medtronic Saudi Arabia	2	

* 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.