



SBED Weekly Update 13-Feb-18

Dear,
SBED team is pleased to inform you that **36** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 2/5/2018 to 2/11/2018
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	Medline Fluid Management – MED-SOFT 3-liter suction liners	2/6/2018	Medline Industries Inc....	Ikar Establishment	FSN	https://nc.mdr
-----	--	----------	----------------------------	--------------------	-----	---

New	IRRAflow Control Unit ICCU 020	2/6/2018	IRRAS AB Inc.	N/A	FSN	https://nc
-----	--------------------------------	----------	---------------	-----	-----	-------------------------------------

Assistive products for persons with disability

New	ACE(TM) BRAND, ULTRA LITE ANKLE brace	2/11/2018	3M Health Care Ltd	3M company	2	https://nc
-----	---------------------------------------	-----------	--------------------	------------	---	-------------------------------------

Dental devices

New	Implant Direct, INTERACTIVE HEALING COLLAR	2/8/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	2	https://nc.mdr
-----	--	----------	---	---	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
-----------	---------------	-----------	--------------	------------	-------	------

Diagnostic and therapeutic radiation devices

	New	Centricity Universal Viewer with PACS-IW foundation 6.0 and Centricity PACS-IW with Universal Viewer	2/6/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr.sfda.gov.s
--	-----	--	----------	---------------	---------------	-----	---

#	New	DynaCAD Breast and Prostate Software Versions 3.4 and 3.5	2/5/2018	Invivo Corporation	Hatem I. Alshedwy Comm. Est.	2	Attac hed
---	-----	---	----------	--------------------	------------------------------	---	-------------------------------

	New	Panoramic Xray Model PC1000, Laser1000	2/7/2018	Panoramic Rental Corp.	N/A	2	https://nc
--	-----	--	----------	------------------------	-----	---	-------------------------------------

	New	Proleus 235, ProleusPLUS	2/6/2018	on Beam Applications S.A	N/A	FSN	A/Ca\
--	-----	--------------------------	----------	--------------------------	-----	-----	-----------------------

	New	Spacelabs Healthcare Xhibit Telemetry Receiver, Model 96280, software version 1.1	2/7/2018	Spacelabs Healthcare Inc	Gulf Medical Co.	2	https://nc.mdr.sfda
--	-----	---	----------	--------------------------	------------------	---	---

	Update	SureSigns VSi, SureSigns VS2+ monitors	2/6/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc
--	--------	--	----------	--------------------	--------------------------------------	-----	-------------------------------------

	New	Syngo.plaza systems.	2/7/2018	Siemens Medical Solutions	Siemens Medical Solution	2	A/Ca\
--	-----	----------------------	----------	---------------------------	--------------------------	---	-----------------------

Electro mechanical medical devices

#	New	Ethernet to Fiber-Optic Converters Used with Mako RIO Systems	2/5/2018	Stryker Communications	Al-Faisaliah Medical System	2	Attac hed
---	-----	---	----------	------------------------	-----------------------------	---	-------------------------------

	New	Philips HeartStart MRx and FR3 Monitor/Defibrillator ,	2/6/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc.mdr
--	-----	--	----------	--------------------	--------------------------------------	-----	---

	Update	Radiometer TCM5 FLEX / BASIC Transcutaneous Monitor ,	2/11/2018	Radiometer America Inc	Salehiya Trading Est.	1	https://nc.mdr
--	--------	---	-----------	------------------------	-----------------------	---	---

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Valleylab FT10 energy platform	2/7/2018	Medtronic SA	Medtronic Saudi Arabia	2	https://nc

In vitro diagnostic devices

New	CD34/CD133 Enumeration Kit, human (IVD)	2/6/2018	Miltenyi Biotec GmbH	Enjaz Medical Modern Company	FSN	https://nc mdr
-----	---	----------	----------------------	------------------------------	-----	--

New	Dimension Vista Calcium (CA) Flex reagent cartridge.	2/11/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://nc mdr
-----	--	-----------	-------------------------------------	----------------------------	---	--

New	EliA anti-TSH-R Well	2/6/2018	Phadia Ltd	ULREHMAN AL GOSAIBI	FSN	A/Ca
-----	----------------------	----------	------------	---------------------	-----	-------------------------

New	ETEST Polymyxin B (PO1024)	2/6/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
-----	----------------------------	----------	----------------	-----------------------------------	-----	-------------------------------------

New	Tosoh Automated Enzyme Immunoassay Analyzer AIA900, Tosoh Sorter 9tray and Tosoh Sorter 19tray	2/5/2018	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	2	https://nc mdr sfda gov.s
-----	--	----------	-------------------	-------------------------------	---	--

#	New	Various In Vitro Fertilization Products	2/5/2018	CooperSurgical Inc..	ATTIEH MEDICO LTD	2	Attac hed
---	-----	---	----------	----------------------	-------------------	---	--

Medical software

New	Syngo.plaza Picture Archiving and Communication System	2/5/2018	Siemens Medical Solutions	Siemens Medical Solutions	2	https://nc mdr
-----	--	----------	---------------------------	---------------------------	---	--

Non-active implantable devices

#	New	Tornier—Salto Talaris Tibial Implants	2/5/2018	Menicon Co. Ltd.	N/A	2	Attac hed
---	-----	---------------------------------------	----------	------------------	-----	---	--

New	611P CT LUCIA Posterior Chamber Hydrophobic Acrylic Lens	2/6/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	FSN	https://nc mdr
-----	--	----------	------------------------	------------------	-----	--

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Excella II Polyaxial Pedicle Screws ,	2/5/2018	Innovasis, Inc	N/A	2	Attac hed
New	Mako Onlay Insert Extractor	2/6/2018	Stryker Orthopaedics	Zimmo Trading Establishment.	FSN	https://nc
New	Signature Ceramic Femoral Head	2/11/2018	Signature Orthopaedics	N/A	2	https://nc
New	Zimmer Natural Nail System Tear Drop Guide Wire	2/11/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc.mdr.

Single-use devices

New	Biatain Ag Cavity Filler	2/7/2018	Coloplast A/S	Hammad Medical Service	2	A/CaV
# Update	CADD(R) Medication Cassette with clamp and female Luer	2/6/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	Attac hed
New	Lumbar Puncture Tray	2/11/2018	Robert Busse & Co. Inc	N/A	2	A/CaV
# New	NAMIC Fluid Management Convenience Kits,	2/5/2018	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac hed
New	Plastic Dignity Low Profile CT Port	2/8/2018	Medical Components, Inc	Farabi Trading Establishment	2	https://nc
New	SURFIT Natura Moldable Durahesive Skin Barrier with Hydrocolloid Flexible Collar	2/7/2018	ConvaTec	Salehiya Trading Est.	2	https://nc.mdr.sfda.
# New	Teleflex Rusch Green Lite Mac 1 Laryngoscope Blades	2/11/2018	Medline Industries Inc....	Ikar Establishment	2	Attac hed

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Unomedical ConvaTec Frazier Suction Handle (included in Foot Pack Health and Lower Extremity Procedure Packs)	2/11/2018	Medline Industries Inc....	Ikar Establishment	2	https://ncmdr.sfda.gov.sa/Se

* 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.