



SBED Weekly Update 04-Sep-17

Dear,
SBED team is pleased to inform you that **27** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/28/2017 to 9/3/2017
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	22 mm Flextube Transport Breathing Systems	8/28/2017	Intersurgical	N/A	2	Attac hed
---	-----	--	-----------	---------------	-----	---	---------------------------

Assistive products for persons with disability

#	New	Sundance Solutions Z-Flo Fluidized Positioners	8/28/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	2	Attac hed
---	-----	--	-----------	---------------------------	------------------------------------	---	---------------------------



#	Update	Sundance Solutions Z-Flo Fluidized Positioners	8/28/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	2	Attac hed
---	--------	--	-----------	---------------------------	------------------------------------	---	---------------------------

New	Universal Arm Support	9/3/2017	Medizin Systeme GmbH	Medical regulations gate	FSN	A/Cal
-----	-----------------------	----------	----------------------	--------------------------	-----	-----------------------

Diagnostic and therapeutic radiation devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Accent/ Anthem, Accent MRI/ Accent ST, Assurity/ Allure and Assurity MRI devices	9/3/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr.sfda
# New	ACUSON S Ultrasound Systems	9/3/2017	SIEMENS	Siemens Medical Solutions	2	Attac hed 
# New	Artis Q and zee Biplane Systems	9/3/2017	SIEMENS	Siemens Medical Solutions	2	Attac hed 
# Update	DR system GU60A	9/3/2017	Samsung Electronics	m M. Al-Mana & Bros. Co	FSN	ttache 
New	NeuViz 64 Multislice CT Scanner System, NeuViz 128 CT Scanner System	9/3/2017	Neusoft Medical Systems	Al Afandi Establishment	2	https://nc.mdr

Electro mechanical medical devices

New	Burn Sheet, sterile 60 x 96	8/30/2017	Certified Safety Mfg Inc..	HEBA Fire & Safety Equip	2	A/Ca
# New	Cystoscopy Bridges and Working Inserts	8/28/2017	Olympus	Salehiya Trading Est.	2	Attac hed 
Update	DBS Lead Depth Stop	9/3/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	A/Ca
# New	IntelliVue Patient Monitors Performing 12-Lead ECG Monitoring	9/3/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attac hed 
# New	Mahurkar Acute Dialysis Catheter Trays	8/28/2017	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed 
# New	TECOTHERM NEO Infant Warming and Cooling Units	9/3/2017	TEC COM GmbH.	Techno-Orbits Establishment	2	Attac hed 
# New	Traxcess 7 Mini Guidewires	8/28/2017	MicroVention Europe S.A.R.L.	white iris est	2	Attac hed 

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Xper Flex Cardio Patient Monitoring Systems	9/3/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attached

In vitro diagnostic devices

New	AQUIOS CL Flow Cytometry System.	8/30/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	https://nc
New	ID-DiaCell	8/30/2017	Bio-Rad ,	ULREHMAN AL GOSAIBI	FSN	A/CaV
New	Remel Wellcolex Colour Shigella Reagent	8/30/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	https://nc
New	Streptex Rapid Latex Agglutination Test.	8/30/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	2	https://nc
New	Sysmex CS-5100 Analyser	8/30/2017	s Healthcare Diagnostics F	AL-KAMAL Import	2	A/CaV


Non-active implantable devices

# New	Norian Drillable Inject	8/28/2017	Synthes GmbH	MAAMOUN TAMER & C	2	ttache
-------	-------------------------	-----------	--------------	-------------------	---	------------------------

Single-use devices

New	AirLife(TM) Arterial Blood Gas (ABG) Sampling Kit	9/3/2017	Vyaire Medical	N/A	FSN	https://nc
New	Kii Abdominal Troacar	8/30/2017	Applied Medical Resources	Dawha Medical	2	A/CaV
# New	Oral Care Products	8/28/2017	Sage Products LLC	Teriag International	2	ttache
Update	Over-Pressure Safety Valves	8/30/2017	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	https://nc

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

- * 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.