



SBED Weekly Update 21-Aug-18

Dear,
SBED team is pleased to inform you that **30** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/13/2018 to 8/18/2018
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
------	---------------	-----------	--------------	------------	-------	------	-----------------

Anaesthetic and respiratory devices

New	AEROtube-ET01-65M-SET, Endotrachealtubus-SET,mit Manschette, einzeln steril verpackt	8/18/2018	HUM GmbH	N/A	FSN	https://nc.mdr	
-----	--	-----------	----------	-----	-----	---	--

New	Arkon Anesthesia Delivery System..	8/14/2018	Spacelabs Healthcare Inc	Gulf Medical Co.	1	https	
-----	------------------------------------	-----------	--------------------------	------------------	---	---------------------------	--

New	Matrx Digital MDM Mixer	8/18/2018	ir Liquide Medical System	N/A	2	A/CaV	
-----	-------------------------	-----------	---------------------------	-----	---	-----------------------	--

Assistive products for persons with disability

New	VitalGo Total Lift Bed	8/14/2018	Vitalgo Inc	N/A	2	A/CaV	
-----	------------------------	-----------	-------------	-----	---	-----------------------	--

Diagnostic and therapeutic radiation devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	iTOVi Tracker/Scanner	8/14/2018	Hudson Scientific LLC	N/A	2	A/Ca\	
New	MEVION S250/MEVION S250i	8/14/2018	Mevion Medical Systems, Inc.	Gulf Medical Co.	2	https	
New	Philips Allura Xper, UNIQ and Centron	8/16/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https	
New	Samsung X-ray systems	8/18/2018	Samsung Electronics	im M. Al-Mana & Bros. C	FSN	A/Ca\	
New	The Infinity M30Ö+	8/18/2018	raeger Medical Systems Ir	Draeger Arabia Co. Ltd.	FSN	A/Ca\	
New	VentriClear	8/14/2018	Cook Inc,	Majal Care for Trading Est	2	A/Ca\	

Electro mechanical medical devices

New	Boston Scientific Guider Softip XF Guide Catheter	8/14/2018	Boston Scientific Cardiac Rhythm Management	FAROUK, MAAMOUN TAMER & COMPANY	2	https	
-----	---	-----------	---	---------------------------------	---	---------------------------	--

In vitro diagnostic devices

New	Alinity ci-series System Control Module (SCM).	8/14/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https	
New	G8 Automated HPLC Analyzer	8/14/2018	Tosoh Bioscience Inc	N/A	2	https	
New	TCube One Step MultiDrug Oral Fluid Test Cube	8/14/2018	GUANGZHOU Wondfo Biotech Co., Ltd.	Regulatory Standards	2	https://nc	
New	UniCel DxH 800 and UniCel DxH 600 Coulter Cellular Analysis System	8/18/2018	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	1	https://nc	
New	Various in vitro fertilisation (IVF) and assisted reproduction technologies (ART) products	8/18/2018	Sage In-Vitro Fertilization Inc - A Cooper Surgical Company	N/A	2	https://nc.mdr.sfda	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
------	---------------	-----------	--------------	------------	-------	------	-----------------

Non-active implantable devices

# Update	AFX Endovascular AAA System	8/13/2018	Endologix Inc	N/A	FSN	Attac	
----------	-----------------------------	-----------	---------------	-----	-----	-----------------------	--

New	rHead, Lateral Assembly and multiple Orthopedic implants	8/14/2018	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	2	https://nc	
-----	--	-----------	---------------------------	------------------------------	---	-------------------------------------	--

New	Spatz3 Adjustable Gastric Balloon System	8/18/2018	SPATZ FGIA, INC..	MEDICAL INNOVATIONS EST.	2	https	
-----	--	-----------	-------------------	--------------------------	---	---------------------------	--

New	TRENDHIP STANDARD CEM.LESS 12/14 SIZE 2	8/18/2018	Groupe Lepine	N/A	FSN	https	
-----	---	-----------	---------------	-----	-----	---------------------------	--

New	VERASENSE ZBH-PSNCREF311-R CR E-F/3-11 Right.	8/18/2018	Orthosensor Inc.	Smith & Nephew inc	2	https://nc	
-----	---	-----------	------------------	--------------------	---	-------------------------------------	--

Ophthalmic and optical devices

New	Alcon LuxOR™ E71 Ophthalmic Microscope Alcon LuxOR™ E71 Q-Vue™ Ophthalmic Microscope	8/18/2018	Alcon Laboratories Inc.	Al Amin Medical Instruments Co. Ltd.	FSN	https://nc.mdr.sfda	
-----	---	-----------	-------------------------	--------------------------------------	-----	---	--

New	Beaver Xstar	8/14/2018	Beaver Visitec International	lin Medical Instruments C	2	A/Ca	
-----	--------------	-----------	------------------------------	---------------------------	---	----------------------	--

New	Stellaris Elite™ Single Port Vitrectomy Cutters in Gauge	8/18/2018	Bausch & Lomb GmbH..	Medical regulations gate	FSN	https://nc	
-----	--	-----------	----------------------	--------------------------	-----	-------------------------------------	--

Reusable devices

New	FLO LOK III Dispenser	8/18/2018	Roche Diagnostics GmbH	el Medical & Trading Co.	FSN	A/Ca	
-----	-----------------------	-----------	------------------------	--------------------------	-----	----------------------	--

Single-use devices

# New	AirLife Manual Resuscitation Devices	8/13/2018	Vyaire Medical, Inc..	Bio Standards	2	Attac	
-------	--------------------------------------	-----------	-----------------------	---------------	---	-----------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# Update	Aplicare Povidone Prep Pads Contained in Pro-Vent and Pulsator ABS Kits	8/13/2018	Smiths Medical International Limited	almdar medical Est.	FSN	Attached	
New	Mako Vizadiscs and Vizadisc Hip Tracking Kit	8/18/2018	MAKO Surgical Corp	N/A	2	https	
New	Short Term Haemodialysis Catheters	8/18/2018	Medical Components, Inc	Farabi Trading Establishment	2	https	
New	Zytologiebürste Einweg	8/18/2018	ENDO Medizinstechnik e.I	N/A	FSN	A/Ca\	

- * 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.