



**SBED Weekly Update** 13-Nov-18

Dear,  
SBED team is pleased to inform you that **31** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 11/5/2018 to 11/11/2018  
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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**Active Implantable Devices**

New	SQ-RX™ Pulse Generator	11/6/2018	Boston Scientific Ltd	MAAMOUN TAMER & C	FSN	<a href="#">A/Ca\</a>	
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**Dental devices**

New	3M Fast Release Varnish	11/7/2018	3M Health Care Ltd	3M company	2	<a href="#">A/Ca\</a>	
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New	IMPAK ELASTIC ACRYLIC RESIN LIQUID	11/5/2018	CMP Industries, Llc	N/A	2	<a href="#">https</a>	
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New	ParaPost Plus Posts	11/7/2018	Coltene Whaledent Inc.	Asnan Medical Services	2	<a href="#">A/Ca\</a>	
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**Diagnostic and therapeutic radiation devices**

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Centricity Universal Viewer with PACSIW foundation 6.0.x, entricity PACSIW with Universal Viewer version 5.0.x with PACSIW foundation	11/7/2018	GE Healthcare	GE Healthcare	2	<a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>	
New	D2RS / DX-D800 / Visionary DRF	11/5/2018	Stephanix S.A.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="https">https</a>	
New	Maternal and Fetal Monitor	11/6/2018	Sunray Medical Apparatus Co., Ltd..	N/A	FSN	<a href="https">https</a>	
New	SP4S, SP4S option AT, SP4S option AP	11/11/2018	Stephanix S.A.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="https">https</a>	
New	Telemis-Medical Software ,	11/11/2018	Telemis S.A.	N/A	FSN	<a href="https">https</a>	
New	Vereos PET/CT, Software version 2.0.1.	11/6/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https">https</a>	
New	Xsense DR	#####	General Medical Merate SpA	Bio Standards	FSN	<a href="A/Ca">A/Ca</a>	
Update	Ysio and Ysio MAX systems and Multix Fusion Analog , Multix Fusion Digital Portable , Multix Fusion Digital Integrated and Multix Fusion Digital Wireless	11/5/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://ncmdr.sfda.gov.sa/Sec">https://ncmdr.sfda.gov.sa/Sec</a>	

### Electro mechanical medical devices

New	Philips Prodiva MRI System	11/5/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https">https</a>	
New	Volumat MC Agilia	11/7/2018	Fresenius Kabi Ltd	Gulf Medical Co.	2	<a href="A/Ca">A/Ca</a>	

### In vitro diagnostic devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
Update	ARCHITECT Free T3 Reagent Kit, ARCHITECT Total T3 Reagent Kit v ,	11/5/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>	
Update	ClinRep Complete Kit for Antiepileptics in Serum / Plasma with UHPLC	11/11/2018	Recipe Chemicals & Instruments GMBH	NAIZAK GLOBAL ENGINEERING LAB SYSTEMS	FSN	<a href="https://nc">https://nc</a>	
Update	CoaguChek XS Test Strips INST 48CT	11/7/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https">https</a>	
Update	Hematek Wright-Giesma Stain Paks and Modified Wright Stain Paks	11/11/2018	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	<a href="https://nc">https://nc</a>	
New	Human IgM Kit for use on SPAPLUS ,	11/11/2018	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https">https</a>	
New	LinkSeq HLA	#####	Linkage Biosciences Inc.	rabi Trading Establishme	FSN	<a href="A/Ca">A/Ca</a>	
New	VITROS 3600, 4600, 5600, 7600 & 5,1FS ,	11/11/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	<a href="https">https</a>	

### Non-active implantable devices

New	Avenir Muller Stem (Std./Lateral)	11/11/2018	Zimmer, INC....	Medical Regulations Gate	2	<a href="https">https</a>	
New	Cervical locking cage + Lumbar locking cage	11/6/2018	EUROSPINE SARL	N/A	2	<a href="https">https</a>	

### Ophthalmic and optical devices

New	Plex Elite 9000 ,	11/5/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	<a href="A/Ca">A/Ca</a>	
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### Reusable devices

New	CODAN Guard V86, V86-R	11/5/2018	edizinische Geraete GmbH	Alwan Alnoor Trading Est	2	<a href="A/Ca">A/Ca</a>	
New	Endoform Dermal Template	11/7/2018	Aroa Biosurgery	N/A	2	<a href="https">https</a>	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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### Single-use devices

New	4-Way Stopcock w/MLL, Adapter DBL Male and Female LL	11/7/2018	Argon Medical Devices	Al Amin Medical Instruments Co. Ltd.	2	<a href="https://nc">https://nc</a>	
New	ATRIUM PVC Thoracic Catheter	11/5/2018	Atrium Medical Corporation	Gulf Medical Co.	FSN	<a href="https">https</a>	
New	NOVOSYN VIOLET 3/0(2)4X70CM HR22TO	11/5/2018	B Braun Surgical SA	Gulf Medical Co.	FSN	<a href="https">https</a>	
# New	Protexis Neoprene Surgical Gloves	11/8/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	FSN	<a href="Attac">Attac</a>	
New	Transbronchial Aspiration Needle SU	11/6/2018	ENDO-FLEX GmbH	First Gulf Co.	FSN	<a href="https">https</a>	

\* 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.