



Dear,

SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 9/3/2018 to 9/9/2018  
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

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

New	CentriMag Acute Circulatory Support System Motor	9/9/2018	Abbott Cardiovascular and Neuromodulation	Arabian Trade House Est.	FSN	<a href="https://nc">https://nc</a>	
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**Anaesthetic and respiratory devices**


New	fabian Therapy evolution.	9/3/2018	utronic Medical Systems A	Salehiya Trading Est.	FSN	<a href="#">A/Ca\</a>	
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**Assistive products for persons with disability**

New	ARCUS treatment tables...	9/9/2018	Getinge Disinfection AB	Gulf Medical Co.	FSN	<a href="#">A/Ca\</a>	
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New	Citadel Plus (Fortress) Power Drive software version V1.17	9/9/2018	Arjo Huntleigh - electric beds	Gulf Medical Co.	FSN	<a href="https://nc">https://nc</a>	
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**Diagnostic and therapeutic radiation devices**

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	B20/B20i/B40/B40i (Bx0), and B105/B125 (B1x5) patient monitors	9/9/2018	GE Healthcare	GE Healthcare	FSN	<a href="https://nc">https://nc</a>	
New	CARESCAPE B450, B650, and B850 (Bx50) monitors	9/9/2018	GE Healthcare	GE Healthcare	FSN	<a href="https">https</a>	
New	CoaguChek (XS PT, XS PT PST, and PT) strips	9/3/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https">https</a>	
New	Cobas e 411 analyzer	9/3/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	<a href="A/Ca">A/Ca</a>	
# New	IntelliVue Information Center iX Central Monitoring Systems	9/3/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="Attac hed">Attac hed</a>	
New	Philips Efficia DFM100 Defibrillator/ Monitor	9/9/2018	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="https">https</a>	

### Electro mechanical medical devices

# New	care-e-vac 3 Battery and AC-Powered Portable Aspirators	9/3/2018	Ohio Medical Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="Attac hed">Attac hed</a>	
New	RROW Pediatric TwoLumen Central Venous Catheterization Kit with Blue FlexTip ARROWgard Blue Cathe	9/4/2018	Arrow International Inc	Gulf Medical Co.	2	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>	

### Healthcare facility products and adaptations

# New	General Utility Trays	9/3/2018	Custom Healthcare System	N/A	FSN	<a href="ttache">ttache</a>	
# New	Heavy Duty Safety Switches	9/3/2018	Eaton Corp	N/A	2	<a href="Attac">Attac</a>	

### In vitro diagnostic devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	400-002-C-MAX - Bordetella Speciation Plus Toxin - OSR for BD MAX	9/3/2018	BioGX BV	N/A	FSN	<a href="https://nc">https://nc</a>	
New	Alinity hq Analyzer..	9/9/2018	Abbott	Supplies & Services Co.Ltd	FSN	<a href="A/Ca">A/Ca</a>	
New	Alinity s System..	9/9/2018	Abbott	Supplies & Services Co.Ltd	FSN	<a href="A/Ca">A/Ca</a>	
New	VITEK 2 AST-P640 and AST-P655	9/3/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https">https</a>	
New	VITEK 2 Gram Positive, Cefoxitin Screen and AST for Oxacillin	9/4/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	1	<a href="https://nc">https://nc</a>	

### Non-active implantable devices

New	GENESIS II NONPOROUS CRUCIATE RETAINING FEMORAL COMPONENT, SIZE 6 RIGHT	9/4/2018	Smith & Nephew inc	Smith & Nephew inc	2	<a href="https://nc.mdr">https://nc.mdr</a>	
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# New	Zenith Alpha Thoracic Endovascular Grafts..	9/3/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	2	<a href="Attac">Attac</a>	
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### Ophthalmic and optical devices



New	Johnson and Johnson Vision Care 1 Day ACUVUE MOIST	9/4/2018	Johnson & Johnson Vision Care	Allied Medical International	2	<a href="https://nc">https://nc</a>	
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New	Peek Acuity Pro App	9/3/2018	Peek Vision Ltd	N/A	FSN	<a href="A/Ca">A/Ca</a>	
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### Single-use devices

# New	Bifuse Transfer Sets	9/3/2018	ICU Medical, Inc	AL-KAMAL Import	2	<a href="ttache">ttache</a>	
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New	Endocavity Needle Guide	9/3/2018	Avco Medical Instruments I	Majal Care for Trading Est	FSN	<a href="A/Ca">A/Ca</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Gripper Plus needle, PORT-A-CATH Plastic Hub Bent Needle	9/3/2018	Smiths Medical International Limited	almdar medical Est.	FSN	<a href="https://nc">https://nc</a>	
# New	Medical Tubing with Cortiva BioActive Surface	9/3/2018	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">Attac</a>	
# New	Nexiva Closed IV Catheter Systems	9/3/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	<a href="#">Attac</a>	
New	Transplant-Aspiration Needle, Biopsy Cannula SPI-CUT	9/3/2018	SOMATEX® Medical Technologies GmbH	digital warranty investment co. ltd	FSN	<a href="https://nc">https://nc</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.