



SBED Weekly Update 05-Sep-18

Dear,
SBED team is pleased to inform you that **26** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/28/2018 to 9/2/2018
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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Anaesthetic and respiratory devices

New	BE-HLS 7050# HLS Set Advanced 7.0	8/28/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	https	
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Assistive products for persons with disability

New	M300 PS, C300 PS, C350 PS, C500 PS, (PS Seating only)	8/30/2018	Permobil AB	N/A	2	https ://nc	
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Diagnostic and therapeutic radiation devices

New	DX-D 600 Digital Radiography Systems	8/30/2018	AGFA Corp.	Gulf Medical Co.	2	https	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	TrueBeam, TrueBeam STx, VitalBeam and EDGE treatment delivery systems ,	8/29/2018	Varian Medical Systems	Varian Medical Systems Arabia Commercial Limited	FSN	https://ncmdr	

Electro mechanical medical devices

New	AlignRT Plus/OSMS system ,	8/30/2018	Vision RT	N/A	2	https	
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New	da Vinci S/Si 8 mm	8/29/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	A/Ca	
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# New	HeartStart Infant/Child SMART Defibrillator Pads Cartridges	8/28/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	Attached	
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New	MiniMed™ remote controller (MMT-500 or MMT-503)	8/28/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc	
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New	Organ Care System (OCS) Heart system - OCS Heart Console	8/30/2018	TransMedics	N/A	2	https://nc	
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# New	PRISMAFLO II and PRISMAFLO II S Blood Warmer Heating Profiles	8/30/2018	Stihler Electronic GmbH	Baxter AG	2	Attached	
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New	Therakos Cellex Photopheresis System	8/30/2018	Therakos Inc	Arabian Medical and Hospital Supplies Co.	2	https	
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New	Tools Database v1.288 CD ,	8/29/2018	Medtronic SA	Medtronic Saudi Arabia	2	https	
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Healthcare facility products and adaptations

# New	Square D Brand General Duty Safety Switches	9/2/2018	Schneider Electric SA	N/A	2	Attached	
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In vitro diagnostic devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Aptio Automation and StreamLAB Automation.	8/30/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	1	https://nc.mdr.sfda.gov.sa/	
# New	GPS III and Plasmax Kits	9/2/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	ttache	
# New	Hematek Wright-Giesma Stain Paks and Modified Wright Stain Paks	8/30/2018	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	FSN	Attac hed	
New	Pastorex Meningitis - reagent R4 (Streptococcus pneumoniae latex - green cap bottle).	8/30/2018	Bio Rad.	Al-Jeel Medical & Trading Co. LTD	2	https://nc.mdr.sfda.gov.sa/	
New	VITROS 5600 Integrated System ,	8/29/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https://nc.mdr.sfda.gov.sa/	
New	Xpert Xpress Flu/RSV assay ,	8/30/2018	Cepheid	ABDULLA FOUAD HOLDING COMPANY	2	https://nc.mdr.sfda.gov.sa/	

Medical software

New	Cerner Dosage Calculator used via PowerOrders or Pharmacy Medication Manager	8/30/2018	CERNER COR	Bio Standards	2	https://nc.mdr.sfda.gov.sa/	
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Non-active implantable devices

New	Hoffmann Limb Reconstruction Frame (LRF) System Hexapod Struts	8/30/2018	Stryker Europe	Al-Faisaliah Medical System	2	https://nc.mdr.sfda.gov.sa/	
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Ophthalmic and optical devices

New	Leica M525 F20	8/29/2018	Leica Microsystems Inc.	I-Faisaliah Medical Syster	FSN	A/Ca	
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Reusable devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Broach Handles for rasp used in orthopaedic surgery	8/30/2018	Evolutis	N/A	2	https://nc	

Single-use devices

#	New	Covidien EEA Circular Staplers with Tri-Staple Technology	8/30/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed		
	New	Jelco ViaValve safety I.V. catheter	8/30/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	https		
#	New	TurboHawk Peripheral Plaque Excision Systems	8/30/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed		

* 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.