



SBED Weekly Update

24-Jul-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 7/16/2018 to 7/22/2018  
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	MEDUMAT Transport Ventilators	7/16/2018	Weinmann.	Al Khateeb United Trading Est.	2	<a href="#">Attac</a>	
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	New	MONNAL T60, Monnal T60 JP	7/18/2018	Air Liquide Medical Systems	N/A	FSN	<a href="#">https</a>	
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**Assistive products for persons with disability**

	New	Molift 2-point Sling Bar	7/18/2018	Etac	Medicare Center	FSN	<a href="#">A/Ca\</a>	
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**Diagnostic and therapeutic radiation devices**


#	New	AXIOM Artis, Artis zee, Q, and Q.zen Systems	7/22/2018	Siemens Medical Solutions	Siemens Medical Solutions	FSN	<a href="#">Attac</a>	
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	New	Nova	7/18/2018	Sedecal S.A	GE Healthcare	FSN	<a href="#">A/Ca\</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Power supply (LPS) for LCD monitor (Version 1.0 and 1.1)	7/19/2018	NordicNeuroLab AS	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>	

### Electro mechanical medical devices

New	da Vinci Xi A70_P8_B622 system software	7/18/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	<a href="https">https</a>	
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# New	M530 OHX Microscope Systems	7/16/2018	Leica Microsystems Inc.	Al-Faisaliah Medical System	2	<a href="Attac">Attac</a>	
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Update	Pentax Video Duodenoscope..	7/18/2018	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd	2	<a href="https">https</a>	
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### In vitro diagnostic devices

New	Anti-Jk	7/18/2018	DiaMed GmbH.	ULREHMAN AL GOSAIBI	FSN	<a href="A/Cal">A/Cal</a>	
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New	Atellica IM 1300 Analyzer, Atellica IM 1600 Analyzer, Atellica CH 930 Analyzer, Atellica Sample Handler	7/18/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https://nc.mdr">https://nc.mdr</a>	
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# New	Calibration Verification Material (CVM) of Blood Gas, Electrolyte, Total Hemoglobin, nBilirubin, and Metabolite Systems used with RAPIDLab Blood Gas and RAPIDPoint Systems	7/22/2018	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	<a href="Attached">Attached</a>	
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New	DS9800 Bond Polymer Refine Detection	7/19/2018	Leica Microsystems, Inc.	Salehiya Trading Est.	FSN	<a href="https">https</a>	
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New	Monoclonal Mouse Anti-Human MSH2 FE11	7/19/2018	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	FSN	<a href="https">https</a>	
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New	VIDAS CA 15-3	7/18/2018	bioMerieux Inc	el Medical & Trading Co.	FSN	<a href="A/Cal">A/Cal</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	VITROS MicroWell Assays	7/18/2018	Ortho-Clinical Diagnostics	Photographic Supplies C	FSN	<a href="#">A/Ca</a>	

New	Xpert MTB/RIF Ultra	7/18/2018	Cepheid	A FOUAD HOLDING CO	FSN	<a href="#">A/Ca</a>	
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### Medical software

New	Health Harmony Mobile	7/18/2018	tel-GE Care Innovations LI	N/A	2	<a href="#">A/Ca</a>	
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### Non-active implantable devices

#	New	CD HORIZON Solera Spinal System Screws	7/22/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="#">Attac</a>		
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New	COPAL knee moulds size L	7/19/2018	Heraeus Medical GmbH	in Medical Instruments C	FSN	<a href="#">A/Ca</a>	
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New	Fx SOLUTIONS CENTERED HEAD	7/18/2018	Fx Solutions	N/A	2	<a href="#">https</a>	
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New	Persona Partial Knee System Spacer Block Alignment Tower	7/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	<a href="#">https://nc</a>	
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New	The UNICP bone fixation system	7/18/2018	Integra LifeSciences	Bio Standards	2	<a href="#">https</a>	
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#	New	UL400 UroLift Systems	7/16/2018	Teleflex Medical	im M. Al-Mana & Bros. C	2	<a href="#">ttache</a>		
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### Single-use devices

#	New	Arrow HANDS-OFF Multi-Lumen Central Venous Catheters with Blue FlexTip	7/22/2018	Teleflex Medical..	Gulf Medical Co.	FSN	<a href="#">Attac</a> <a href="#">hed</a>		
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New	BeeSana Mullkomprese; 5x5 cm, 8-fach	7/19/2018	Meditrade GmbH	N/A	FSN	<a href="#">https</a>	
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New	Chorion Villus Biopsy Needle Set	7/19/2018	Cook Inc,	Majal Care for Trading Est.	FSN	<a href="#">https</a>	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Degania Silicone Temperature-Sensing Catheters in Covidien Kits	7/22/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attached</a>	
New	JELONET 15CM X 2M CTN 12 (JOAR)	7/19/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="#">https</a>	
New	OrthoPat reservoirs	7/18/2018	Haemonetics Corp.	Arabian Trade House Est.	FSN	<a href="#">A/Cal</a>	
New	Trocar catheter	7/19/2018	P J Dahlhausen & Co	First Medical co. Ltd.	FSN	<a href="#">A/Cal</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.