



SBED Weekly Update

27-Nov-18

Dear,

SBED team is pleased to inform you that **21** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/20/2018 to 11/25/2018
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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Dental devices

New	Endosseous dental implant abutment	11/21/2018	Straumann Manufacturing, Inc.	Thimar Al Jazirah Healthcare Co.	2	https://nc.mdr	
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Diagnostic and therapeutic radiation devices

New	BoneScapel and SonaStar FS1000 Ultrasonic Surgical Systems	11/22/2018	Misonix, Inc.	Al Amin Medical Instruments Co. Ltd.	2	https://nc.mdr	
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New	CARESCAPE B850 MBC303 monitors	11/20/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr	
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New	Medical image management system	11/20/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Revolution CT Systems with SmartStep Option	11/22/2018	GE Healthcare	GE Healthcare	2	https	

New	UTIPRO PLUS	#####	Noventure S.L.	N/A	FSN	A/Ca	
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New	Xper Flex Cardio Physiomonitring System	11/21/2018	Invivo Corporation	Hatem I. Alshedwy Comm. Est.	2	https	
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Electro mechanical medical devices

New	Flex Cardio (Model FC2010) devices	11/21/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
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New	Reprocessed LASSO NAV eco Electrophysiology Catheter	11/21/2018	Stryker Instruments..	Johnson & Johnson Medical Saudi Arabia Limited	2	https://nc	
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Hospital hardware

Update	EMS - Model 6390 Power-LOAD Cot Fasteners	11/20/2018	Stryker	Al-Jeel Medical & Trading Co. LTD	2	https	
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In vitro diagnostic devices

New	AIA2000 Analyzer	#####	Tosoh Corporation	A FOUAD HOLDING CO	2	A/Ca	
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Update	Lot-to-Lot Variability When Using Dimension® Lipase (LIPL)	11/21/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc	
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New	Multiple Alinity i Reagents-	11/25/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https	
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New	Recall AIA900 Analyzer	#####	Tosoh Corporation	A FOUAD HOLDING CO	2	A/Ca	
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New	STACLOT LA (REF. 00600).	#####	Diagnostica Stago	pplies & Services Co.Ltd	2	A/Ca	
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Medical software

New	Insulia Diabetes Management Companion	11/21/2018	Voluntis	N/A	2	https	
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Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link	Affected Yes/No
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Non-active implantable devices

New	The Affixus Hip Fracture Nail System	11/21/2018	Zimmer, INC...	Medical Regulations Gate	2	https://ncmdr.gov	
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Single-use devices

New	FG107 Intravitreal Procedure Pack #1 and FG110 Intravitreal Procedure Pack #2A	11/22/2018	House With No Steps	N/A	2	https://ncmdr.gov	
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New	L25 Needle Guide Bracket	#####	ivco Medical Instruments I	Majal Care for Trading Est	FSN	A/Cal	
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New	NOSOCOMIA PREDESINFECTANT INSTRUMENTS	11/21/2018	PRODENE KLINT LABORATOIRES	N/A	2	https://ncmdr.gov	
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New	Powdered Surgical Gloves	#####	American Contract Systems, I	N/A	2	A/Cal	
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- * 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.sfd.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.