



SBED Weekly Update 30-Oct-18

Dear,
SBED team is pleased to inform you that **39** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/22/2018 to 10/28/2018
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	Platinum Implantable Cardiac Defibrillators and Cardiac Resynchronization Therapy Defibrillators	10/22/2018	LivaNova PLC	cigalah group	FSN	Attached	
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Anaesthetic and respiratory devices

New	CARESCAPE R860 Inspiratory Safety Guard	10/24/2018	GE Healthcare	GE Healthcare	2	https	
New	Disposable Smooth Interior Tubing	10/23/2018	A M Systems Inc	N/A	2	https	
New	Medical Air Ensure	#####	raeger Medical Systems Ir	Draeger Arabia Co. Ltd.	FSN	A/Cal	

Diagnostic and therapeutic radiation devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
Update	AccuChek Aviva Plus Test Strip	10/22/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	https://nc.mdr	
New	ASOBYGYN Information System version 7.824.x	10/23/2018	AS Software, Inc.	N/A	2	https://nc.mdr	
New	Biograph mMR with software version syngo E11P when using BodyCOMPASS	10/23/2018	SIEMENS	Siemens Medical Solutions	2	https://nc.mdr	
# New	BrightMatter Guide 1.5 Systems	10/22/2018	Synaptive Medical, Inc	N/A	1	Attac	
New	Centricity Universal Viewer 6.0,	10/24/2018	GE Healthcare	GE Healthcare	2	https://nc.mdr	
# Update	Merge Unity software	#####	Merge Healthcare Corp.	N/A	2	ttache	
New	Mindray BeneVision Distributed Monitoring System (DMS)	10/23/2018	Shenzhen Mindray	Salehiya Trading Est.	2	https://nc.mdr	
New	TRINIAS	#####	Shimadzu Medical System:	N/A	2	A/Cal	
Update	Vantage Titan and Vantage Elan MRI Systems	10/28/2018	Canon Europa N.V..	N/A	2	https://nc.mdr	
# New	Vue RIS Data Management Systems	10/22/2018	Carestream Health	Samir Photographic Supplies Co. Ltd.	2	Attac	
Electro mechanical medical devices							
New	HeartStart FR3 Defibrillator	10/24/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https://nc.mdr	
# New	Medfusion 4000 Syringe Infusion Pumps Used with PharmGuard Server Software	10/22/2018	Smiths Medical, Inc	MEDICARE DRUG STORE COMPANY	2	Attac hed	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	THERMOCOOL SMARTTOUCH® SF Uni-Directional Navigation Catheter & THERMOCOOL SMARTTOUCH® SF Bi-Directional Navigation Catheter	10/23/2018	Biosense Webster Inc.	Johnson & Johnson Medical Saudi Arabia Limited	FSN	https://nc.mdr.sfga.gov.sa/Secure/	

# New	Thermoset Injectate Delivery Systems ,	10/22/2018	ICU Medical, Inc	AL-KAMAL Import	2	Attac	
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Healthcare facility products and adaptations

# New	Essity Professional Tork Premium Hand Soap	10/22/2018	Essity Professional Hygiene North America	N/A	2	Attac	
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In vitro diagnostic devices

New	Alinity ci-series System Control Module (SCM)..	10/23/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https://nc.mdr.sfga.gov.sa/Secure/	
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New	API NH 10GALERIES+10MILIEUX	10/23/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr.sfga.gov.sa/Secure/	
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Update	ARCHITECT HAVAb-IgG Reagent Kit, ARCHITECT HAVAb-IgM Reagent Kit, Alinity i HAVAb IgG Reagent Kit	10/23/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc.mdr.sfga.gov.sa/Secure/	
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New	Gibco	#####	Life Technologies Limited.	ntegrated Gulfbiosystem:	2	A/Ca\	
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New	iChemVELOCITY Urine Chemistry strips ,	10/24/2018	IRIS Diagnostics	Al-Jeel Medical & Trading Co. LTD	2	https://nc.mdr.sfga.gov.sa/Secure/	
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New	IM Abbott Alinity ciseres (abdicqii) accessory driver	10/28/2018	Abbott	Medical supplies & Services Co.Ltd	2	https://nc.mdr.sfga.gov.sa/Secure/	
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# Update	Kaluza C Flow Cytometry	#####	Beckman Coulter	el Medical & Trading Co.	FSN	ttache	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Liquid Cardiac Controls	#####	Radox Laboratories Ltd.	Bio Standards	FSN	ttache	
New	NUCLISENS Lysis Buffer. An in vitro diagnostic medical device (IVD).	10/24/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc	
New	Reverse T3 RIA	#####	meditec Diagnostics Gmk	N/A	2	A/CaV	

Medical software

# New	PeerVue Web Servers	#####	Change Healthcare	N/A	2	ttache	
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Non-active implantable devices

# New	Compress Devices and Instruments	10/22/2018	Zimmer, INC...	Medical Regulations Gate	2	Attac	
New	CryoPatch SG Pulmonary HemiArtery	10/24/2018	CryoLife, Inc.	Almarfa Medical	2	https	
New	GII Distal Cutting Blocks	#####	Smith & Nephew inc	Smith & Nephew inc	FSN	A/CaV	
New	LEGION A/P FEMORAL CUTTING BLOCK	10/28/2018	Smith & Nephew inc	Smith & Nephew inc	2	https	
New	MiniMAX CEMENTLESS ANATOMICAL STEM	10/24/2018	Medacta International SA	N/A	2	https	

Single-use devices

# Update	Hospira Flexible Intravenous Containers Containing Dextrose and Sodium Chloride	10/22/2018	ICU Medical, Inc	AL-KAMAL Import	2	Attac hed	
New	McKesson Insulin Syringe 0.3mL	10/23/2018	Cypress Medical Products.	N/A	2	https	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Mon-a-Therm Foley catheters with temperature sensors,,	10/24/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc	
New	OriGen Reinforced Dual Lumen Cannula	10/24/2018	OriGen Biomedical	Arabian Trade House Est.	2	https	

* 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.