



SBED Weekly Update 20-Nov-18

Dear,
SBED team is pleased to inform you that **47** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/12/2018 to 11/18/2018
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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Assistive products for persons with disability

New	Flexmobil Forma, Miniflex Forma	11/15/2018	Eurovema AB	N/A	2	https	
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New	Uresta Bladder Support	#####	Southmedic Inc	althcare Systems Trading	2	A/Ca	
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Diagnostic and therapeutic radiation devices

# Update	CoaguChek (XS PT, XS PT PST, and PT) strips	11/12/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	Attac	
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New	Kodak DirectView DR 7500 System	11/12/2018	Carestream Health	Samir Photographic Supplies Co. Ltd.	2	https	
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New	Medtronic Navigation	#####	Medtronic SA	Medtronic Saudi Arabia	2	A/Ca	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Neurosign V4 Systems	#####	Magstim Company Limited	ATTIEH MEDICO LTD	2	ttache	
New	Philips HeartStart MRx M3538A	11/12/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
# New	R. Test Evolution 4 Monitors	11/18/2018	Novacor	N/A	2	Attac	
# New	RadPRO Mobile 40kW Digital X-Ray Systems	11/12/2018	Canon Inc	N/A	2	Attac	
# Update	Ysio and Ysio MAX systems and Multix Fusion Analog , Multix Fusion Digital Portable , Multix Fusion Digital Integrated and Multix Fusion Digital Wireless	11/12/2018	SIEMENS	Siemens Medical Solutions	FSN	Attac hed	

Electro mechanical medical devices

# New	da Vinci SP Surgical System Instrument Arm Drapes	11/18/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	Attac hed	
# New	da Vinci SP Surgical Systems	11/18/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	Attac	
# New	Datascope Intra-Aortic Balloon Pumps	11/12/2018	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	2	Attac	
New	Efficia 3/5 ECG Trunk Cable, AAMI/IEC	11/15/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
New	Espiner Tissue Retrieval System..	11/15/2018	Fannin UK Ltd	TRUSTMED	2	https	
# New	HORIZON E-z Arms Used with HORIZON E-z Cool Coils	11/12/2018	The Magstim Company Limited	ATTIEH MEDICO LTD	2	Attac hed	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
Update	Jaundice Meter JM-103 and JM-105 Out of Range Indication	11/15/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	https://nc	

# Update	MONTERIS MEDICAL NEUROBLATE SYSTEM	11/18/2018	Monteris Medical Corp	N/A	1	Attac	
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In vitro diagnostic devices

New	Androstenedione ELISA	11/12/2018	Tecan Sales Austria GmbH	Samir Photographic Supplies Co. Ltd.	FSN	https	
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New	BioFire FilmArray Meningitis/Encephalitis (ME) Panel	11/15/2018	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc	
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# New	Brazier's CCEY Agar	#####	Fannin UK Ltd	TRUSTMED	2	ttache	
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# New	Eurotrol HemoTrol Hemoglobin Controls	11/12/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	Attac	
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# New	Eurotrol HemoTrol Hemoglobin Controls..	11/15/2018	HemoCue A B	Raez Environmental System & Advanced	2	Attac	
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New	FoodPrint Microarray 200+ Food IgG.	11/12/2018	Cambridge Nutritional Sciences Ltd	AL OSOOL MEDICAL TRADING COMPANY	2	https	
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New	HEA Precise Type Beadchip Kit and RHD Beadchip Kit, CE.	11/12/2018	BioArray Solutions Ltd.	Medical supplies & Services Co.Ltd Mediserv	2	https://nc	
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# New	HemoTrol Hemoglobin Controls	11/18/2018	Eurotrol B.V	Raez Environmental System & Advanced	2	Attac	
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New	VITROS Immunodiagnostic Products Vitamin B12 Reagent Pack	11/12/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	https://nc.mdr	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
Update	VITROS MicroWell Assays, Folate, Free PSA	11/12/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https	

Medical software

New	G-Series, E-Series and BCM SCC RAM Inspection and Installation	11/12/2018	Abbott Diagnostic International Ltd	Medical supplies & Services Co.Ltd Mediserv	FSN	https	
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New	Image orientation labels with scenario.	11/12/2018	Siemens Medical Solutions	Siemens Medical Solutions	FSN	https	
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Non-active implantable devices

New	3.2mm Proximal Reamer/Cannulated Drill	11/15/2018	Arthrex, Inc	Medical Regulations Gate	2	https	
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New	FlareHawk	#####	Integrity Implants Inc.	N/A	2	A/Cal	
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Update	H3 Poly Inlay	#####	DT MedTech	N/A	FSN	A/Cal	
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Update	Intramedullary Fixation	#####	Zimmer, INC....	Medical Regulations Gate	2	A/Cal	
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New	OviTex Reinforced BioScaffold	11/15/2018	Aroa Biosurgery	N/A	2	https	
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New	ZCORE Porcine Xenograft Particulate	11/15/2018	OSTEOGENICS BIOMEDICAL,INC.□	Ahmad Abdullah Alzoman Est. for trading	FSN	https	
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Ophthalmic and optical devices

New	Mölnlycke® Suction & Irrigation Set	11/15/2018	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	2	https	
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# Update	Plex Elite 9000	#####	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	ttache	
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Single-use devices

# New	Arrow EZ-IO 45 mm Needle + Stabilizer Kits	11/12/2018	Teleflex Medical...	First United Medical Services Co Ltd	2	Attac	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	Diazepam Injections in Carpuject Syringes	11/12/2018	Hospira Inc	AL-KAMAL Import	2	Attac	
# New	EpiPen and EpiPen Jr Auto-Injectors	11/12/2018	Pfizer Limited	N/A	2	Attac	
# New	Perfusion Tubing Systems Containing Stopcocks and Stopcock Manifolds	11/18/2018	LivaNova PLC	cigalah group	2	Attached	
# New	PneumoClear CO2 Conditioning Insufflators	11/18/2018	Stryker Endoscopy	Al-Faisaliah Medical System	2	Attac	
# New	PneumoClear Heated High-Flow Tube Sets	11/12/2018	Stryker Endoscopy	Al-Faisaliah Medical System	2	Attac	
# New	Salem Sump Dual-Lumen Stomach Tubes	11/12/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	Attac	
New	Saw blades for bone surgery for single use - STERILE	11/15/2018	Gebr. Brasseler GmbH & Co KG (Business Unit Komet Medical)	Johnson & Johnson Medical Saudi Arabia Limited	FSN	https://nc	
New	Simpurity HYDROGEL ABSORBENT SHEET WOUND DRESSING ADHESIVE BORDER	11/15/2018	Safe N Simple, LLC	N/A	2	https://nc.mdr	

* 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.