



SBED Weekly Update

27-Mar-18

Dear,

SBED team is pleased to inform you that **49** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 3/19/2018 to 3/25/2018
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

Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
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Anaesthetic and respiratory devices


New	Elongated Adult Non Rebreather Mask	3/25/2018	Well Lead Medical Co Ltd	N/A	2	https://nc
New	TRAGOE comfort Tracheostomy Tube	3/19/2018	Tracoe medical GmbH	Arabian Trade House Est.	FSN	https://nc

Assistive products for persons with disability


New	DLX-PM75AL-B LiNX Power Modules (used for Bora and Kite PWCs)	3/19/2018	Invacare Corporation..	Nahdi Medical Company	FSN	https://nc mdr
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Diagnostic and therapeutic radiation devices

New	2 MHZ Waterproof OB Probe	3/21/2018	CooperSurgical Inc..	ATTIEH MEDICO LTD	2	https://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	ACUSON SC2000 ultrasound system.	3/19/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc
New	Certain MRI systems with a metal burst disk	3/20/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc
New	DPX-NT, DPX Bravo, DPX Duo, DPX-MD, Prodigy, Prodigy Advance Systems	3/22/2018	GE Healthcare	GE Healthcare	2	https://nc.mdr
# Update	INFINIX VC-I Interventional Angiography Systems	3/25/2018	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	Attac hed 
New	Ingenuity TF PET/CT System with Addonics Mass Storage Device (MSD)	3/19/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https://nc.mdr.sfda

Electro mechanical medical devices

New	The Infinity® Acute Care System and •Standalone Infinity M540 patient monitor.	3/20/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	https://nc.mdr.sfda
# New	APD Luer-Lock Adapters	3/25/2018	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	Attac hed 
New	ARROWgard Blue PLUS	3/25/2018	Arrow International Inc	Gulf Medical Co.	2	A/Ca\
New	ClariVein IC infusion catheter	3/25/2018	Vascular Insights, LLC	Saudi Sicli Company	2	https://nc
Update	J-Plasma Handpieces	3/25/2018	Sovie Medical Corporation	Bio Standards	2	A/Ca\
New	NaturaLyte Liquid Acid	3/19/2018	Fresenius Medical Care.	senius Medical Care Gmt	2	A/Ca\
New	Power PORTACATH	3/21/2018	Smiths Medical ASD Inc..	CARE DRUG STORE COM	2	A/Ca\

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New	VOLISTA StandOP and TRIOP	3/22/2018	MAQUET Inc	Gulf Medical Co.	FSN	https://nc

Hospital hardware

Update	IMRIS ORT100 and ORT300 Operating Room Tables	3/19/2018	Deerfield Imaging	Gulf Medical Co.	2	https://nc.mdr
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In vitro diagnostic devices

New	Chemistry Wash1 REF 10680	3/25/2018	Medica Corporation.	AL OSOOL MEDICAL TRADING COMPANY	2	https://nc
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New	HbA1c FS/ one HbA1c IS	3/19/2018	ys Diagnostic Systems Gr	Ghuyum Scientific Tradir	FSN	A/Ca
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New	HemoCue WBC Diff analysers and WBC Diff Microcuvettes .	3/22/2018	HemoCue AB	Salehiya Trading Est.	2	https://nc.mdr
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New	IH-1000.	3/20/2018	Bio-Rad ,	ULREHMAN AL GOSAIBI	FSN	A/Ca
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New	LK043.L.OPT.(A) - Optilite Beta-2-microglobulin Urine Kit	3/19/2018	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr
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New	RF Latex Reagent	3/21/2018	Stanbio Laboratory, LP	Al Nahir Trading Co	2	A/Ca
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New	Thermo Scientific Remel Neisseria meningitidis Poly A-D 2mL and Neisseria meningitidis Group D 2mL.	3/25/2018	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	2	https://nc.mdr.sfda.gov.s
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New	ZYMUTEST HIA IgGAM	3/21/2018	HYPHEN BioMed	AlKamal Import Office	2	A/Ca
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Laboratory equipment

#	New	MINC Benchtop Incubators	3/25/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	2	Attac hed
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Non-active implantable devices

New	Handles THA (Total Hip Arthroplasty)	3/19/2018	Aesculap	Gulf Medical Co.	FSN	https://nc
New	Apex Knee System	3/21/2018	OMNIlife science	N/A	2	A/Ca
New	balanSys ligament tensor	3/20/2018	Mathys.	Johnson Medical Saudi Ar	FSN	A/Ca
New	Cannulated Screw System	3/21/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca
New	Comprehensive Shoulder System	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
New	JUGGERKNOT	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca
New	LEGION HK FEMORAL WEDGE	3/21/2018	Smith & Nephew inc	Smith & Nephew inc	2	https://nc
New	NEXGEN LPSFLEX MOBILE AND LPSMOBILE BEARING KNEE SYSTEM	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc mdr.
New	ON-X Prosthetic Heart Valve ONXA	3/19/2018	CryoLife, Inc.	Almarfa Medical	FSN	https://nc
New	Pulsar-18, Peripheral self-expanding Nitinol stent system	3/19/2018	BIOTRONIK UK Ltd	WATEEN MEDICAL CO	FSN	https://nc mdr.
New	Ringloc CoCr Modular Femoral Heads	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
New	SnapShot" Fixation System	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
New	Vanguard Complete Knee System	3/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc

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Ophthalmic and optical devices

New	Laser Indirect Ophthalmoscope (LIO) .	3/21/2018	IRIDEX Corporation	Saudi Services & Health Care Co. Ltd.	2	https://nc
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Reusable devices

New	B5 shape TS1 n25 4% L31 Classic sterile	3/20/2018	MICRO-MEGA S.A	Cigalah Group	FSN	https://nc
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Single-use devices

New	Alden Soft contact	3/19/2018	Alden Optical	N/A	2	A/Ca
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New	Covidien LigaSure Exact Dissector Nano-Coated 20.6mm-21cm	3/25/2018	Medtronic SA	Medtronic Saudi Arabia	2	https://nc.mdr
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New	Custom Dialysis Kit	3/22/2018	Merit Medical Systems, Inc	cal Technology Establishr	2	A/Ca
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New	Dermabond " Prineo " System	3/25/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia	2	https://nc
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New	DxTerity Diagnostic Catheter	3/19/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
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New	Infiniti Bracket (Sold as part of CIVCO brand Biopsy Starter Kits and Biopsy Bracket)	3/20/2018	Civco Medical Instruments Inc	Majal Care for Trading Est.	FSN	https://nc.mdr.sfda
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New	REPAIR KIT	3/21/2018	Medical Components, Inc	rabi Trading Establishme	2	A/Ca
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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.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.