



SBED Weekly Update

20-Feb-18

Dear,

SBED team is pleased to inform you that **53** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 2/12/2018 to 2/18/2018
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

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Active Implantable Devices

New	Jarvik 2000 Ventricular Assist System (VAS)	2/13/2018	Jarvik Heart Inc.	International Medical Supplies Company	FSN	https
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New	VNS(R) Therapy Programmer	2/12/2018	LivaNova PLC	cigalah group	2	https
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Anaesthetic and respiratory devices

New	AKO RIO Spare Part Ethernet-Fiber Optic Converter	2/13/2018	MAKO Surgical Corp	N/A	FSN	https://nc
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New	Aurinio LED OP Leuchte	2/13/2018	LUX Medical GmbH & Co.	el Medical & Trading Co.	FSN	A/Ca\
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New	Tissu-Trans	2/18/2018	pert Medical Technologie	N/A	FSN	A/Ca\
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Unitque Temp° Pflege Set 1	2/13/2018	Geratherm Medical AG	AL ARFAJ MEDICAL SERVICE CO.	FSN	https

Assistive products for persons with disability

New	Getinge 86- and 88-series	2/15/2018	Getinge Disinfection AB	Gulf Medical Co.	FSN	A/Ca\
New	SnugFit(R) Expandable Mattress Cover	2/12/2018	LITTLE RAPIDS CORPORATION	N/A	2	https

Dental devices

New	PrimaConnex Implant System	2/18/2018	Keystone Dental Inc.	N/A	2	https
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Diagnostic and therapeutic radiation devices

New	ACUSON SC2000 ultrasound systems	2/15/2018	SIEMENS	Siemens Medical Solutions	1	https
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New	Biograph mMR with software version syngo E11P	2/15/2018	SIEMENS	Siemens Medical Solutions	2	https ://nc
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#	New	Enterprise Imaging Systems	2/13/2018	AGFA Corp.	Gulf Medical Co.	2	
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New	ExacTrac Patient Positioning System	2/15/2018	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	FSN	https
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Update	GC80	2/13/2018	Samsung Electronics	im M. Al-Mana & Bros. C	FSN	A/Ca\
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New	GE TEE probes used with Tristel Trio Wipes System	2/13/2018	GE Healthcare	GE Healthcare	FSN	https
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New	OASIS	2/15/2018	Hitachi Medical Corp	ULREHMAN AL GOSAIBI	2	A/Ca\
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New	RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7)	2/15/2018	RaySearch Laboratories AB	N/A	FSN	https://nc.mdr.sfd.a
New	SOMATOM ... verschiedene Typen mit Somaris 5	2/13/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc
New	TD60 Transmitter Battery Charger	2/12/2018	Shenzhen Mindray	Salehiya Trading Est.	2	https

Electro mechanical medical devices

New	AVID Medical QA Pack	2/12/2018	Avid Medical, Inc.	N/A	2	A/Ca
# New	Berchtold CHROMOPHARE Ceiling-Mounted Surgical Light Systems	2/12/2018	Stryker Communications	Al-Faisaliah Medical System	2	
# New	Berchtold CHROMOPHARE Ceiling-Mounted Surgical Light Systems .	2/13/2018	Stryker Communications	Al-Faisaliah Medical System	2	
New	Bio-Cal Temperature Controller	2/13/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https
New	HeartStart MRx Monitor/Defibrillator	2/12/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	1	https
New	Maquet PowerLED, HLED 700 SF and Volista 600SF Surgical Lighting Systems	2/15/2018	MAQUET Inc	Gulf Medical Co.	2	https://nc
# Update	Medfusion 3500 and 4000 Syringe Infusion Pumps ,	2/12/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	Update	PENTAX Medical ED-3490TK Duodenoscope and inspection of all PENTAX Duodenoscopes	2/12/2018	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	FSN	
	New	Video Cystoscope models ECY1570 and ECY1570K	2/18/2018	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd	2	https

Healthcare facility products and adaptations

	New	Medtronic ANGLED DRILL	2/12/2018	Medtronic SA	Medtronic Saudi Arabia	2	A/Ca\
	New	Spinal & Epidural Anesthesia Tray	2/12/2018	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	https

In vitro diagnostic devices

	New	Alinity ci-series System Control Module (SCM)	2/15/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https
	New	AQUIOS CL Flow Cytometer System.	2/15/2018	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https
	New	ARCHITECT c4000 / c8000 / c16000 cuvette segments	2/15/2018	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	2	https://nc
	Update	AU Lyophilized Chemistry Level 1 Calibrators	2/15/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	https
	New	BORRELIA VIRCLIA IgG MONOTEST	2/13/2018	VIRCELL	ABDULLA FOUAD HOLDING COMPANY	FSN	https
	New	Cortisol Saliva ELISA	2/13/2018	Tecan Sales Austria GmbH	Photographic Supplies C	FSN	A/Ca\
	New	Foetal Haemoglobin Monoclonal Antibody (HBF-1), FITC	2/15/2018	Life Technologies Limited.	Integrated Gulfbiosystems	2	https://nc
	New	Xpert CT/NG.	2/15/2018	Cepheid	LA FOUAD HOLDING CO	2	A/Ca\

Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
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Laboratory equipment

New	Gibson Bioscience Blastomyces dermatitidis Antiserum	2/18/2018	Gibson Laboratories LLC	N/A	2	https://nc
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New	Hologic Panther(R) Fusion	2/15/2018	HOLOGIC NV	el Medical & Trading Co.	2	A/Ca
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Non-active implantable devices

New	Exactech GPS Total Shoulder Application 3.2mm Vix Bit	2/15/2018	Exactech	N/A	2	https://nc
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New	IMPIX MANTA preloaded on holder	2/15/2018	Medicrea International.	Salehiya Trading Est.	FSN	https
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New	iTotal Posterior Stabilized (PS) Knee Replacement System	2/15/2018	ConforMIS	N/A	2	https://nc
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New	Small Pedicle Probe ELL- IN 02 23-N	2/15/2018	SPINEART	Tina Medix Technologies Int. Co.	2	https
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New	thoracolumbosacral pedicle screw system	2/18/2018	OrthoPediatrics Corp	ProMedEx	2	https
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New	Titanium Trochanteric Fixation Nail (TFN)	2/15/2018	Synthes Inc	Isam Economic Co.	2	https
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New	Triathlon Knee System 5mm & 10mm Tibial Augment	2/15/2018	Stryker Orthopaedics	Zimmo Trading Establishment.	FSN	https://nc
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Ophthalmic and optical devices

New	HEINE Standard F.O. Laryngoskopgriff mit LED- Beleuchtung	2/18/2018	HEINE Optotechnik GmbH & Co. KG	Scientific & Medical Equipment House	FSN	https://nc
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Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Agilia Volumat Infusion Set portfolio	2/15/2018	Fresenius Kabi Ltd	gulf Medical Co.	2	https://ncmdr.sfda.gov.sa/Secure/CA/CACompositeListing.aspx
New	Capio™ Suture Capturing Devices (SLIM, Standard, Open Access, RP), Uphold LITE with Capio™ SLIM Vaginal Support System, Pinnacle™ Anterior Pelvic Floor Repair Kit , and Pinnacle LITE Posterior with Capio SLIM Pelvic Floor Repair Kit	2/15/2018	Boston Scientific	Gulf Medical Co.	FSN	https://ncmdr.sfda.gov.sa/Secure/CA/CACompositeListing.aspx
New	Custom Made Tracheostomy Device	2/12/2018	Smiths Medical International Limited	almdaar medical Est.	2	https://ncmdr.sfda.gov.sa/Secure/CA/CACompositeListing.aspx
# New	Disposable Drill Kits ,	2/13/2018	Medical Instrument Corp	Al-Nozha Medical Est	2	https://ncmdr.sfda.gov.sa/Secure/CA/CACompositeListing.aspx
New	SynviscOne	2/18/2018	Sanofi Genzyme	N/A	2	https://ncmdr.sfda.gov.sa/Secure/CA/CACompositeListing.aspx

* 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.