



SBED Weekly Update

08-May-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 4/30/2018 to 5/3/2018
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	INGEVITY MRI extendable/retractable (active fixation) pacing lead	5/3/2018	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr
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Anaesthetic and respiratory devices

New	Dräger Carina Ventilator	5/3/2018	raeger Medical Systems Ir	Draeger Arabia Co. Ltd.	1	A/CaV
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Assistive products for persons with disability

New	Malte, Malte-Outdoor, Marcy	5/1/2018	Schuchmann GmbH & Co. KG	N/A	FSN	https
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Complementary therapy devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	MediVac(TM) Flex Advantage(TM) Suction Canister Liner	5/1/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	https://nc

Diagnostic and therapeutic radiation devices

#	New	Brilliance 64 Computed Tomography Systems	4/30/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	
	New	Diagnostic X-ray system GC80	5/3/2018	SAMSUNG MEDISON CO.,LTD	El Seif Company	FSN	https
	New	FUJIFILM General X-ray System FDR Smart f series	4/30/2018	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	2	https
	New	MR Surgical Suite Table Transfer Release	5/1/2018	GE Healthcare	GE Healthcare	FSN	https
	New	Revolution EVO & Optima CT660, CT670, CT680, CT540 Internal Electrical Cable	4/30/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr
	Update	SOMATOM ... verschiedene Typen mit Somaris 5	5/1/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc

Electro mechanical medical devices

	New	AbViser AutoValve Pressure Monitoring Device	5/3/2018	ConvaTec	Salehiya Trading Est.	FSN	https://nc
	New	Apple-Hunt Secondary Cannula/Pyramidal Tip Trocar	5/3/2018	Cooper Surgical, Inc.	Cure Development International Ltd	2	https://nc
#	New	CARTO 3 Navigation Systems	4/30/2018	Biosense Webster Inc.	Johnson & Johnson Medical Saudi Arabia	2	
	New	Laser Handpiece	5/3/2018	Beijing Syntech Laser Co., Li	N/A	2	A/Ca/

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	Update	Model 8100 Alaris Pump Modules.	5/1/2018	Becton, Dickinson And Company	Medical Regulations Gate	2	
	New	WETFIELD OSHER THERMODOT MARKER, 25GA FINE TIP, CURVED	4/30/2018	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	2	https://nc

Hospital hardware

	New	6381 M1 and 6376 M1 Cot Fastener	5/3/2018	Stryker Communications Corp	Al-Jeel Medical & Trading Co. LTD	2	https
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In vitro diagnostic devices

	New	Accelerate PhenoTest BC kit	4/30/2018	Accelerate Diagnostics Inc	Creative Healthcare Establishment	2	https
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	New	CELLSEARCH Circulating Tunor Cell Kit (Epithelial)	4/30/2018	Menarini Silicon Biosystems	N/A	2	https
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	New	MagNA Pure 24 System	5/3/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	A/Ca
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	New	NEOselect/NEOliquid - POST PCR Box (-20°C storage)	5/1/2018	New Oncology GmbH	N/A	FSN	https://nc
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	New	PTS Panels CHOLGLU Test Strips	4/30/2018	Polymer Technology Systems, Inc...	Abdulrauf Ibrahim Batterjee & Bros.	2	https
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	New	VITEK® MS	5/1/2018	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca
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Non-active implantable devices

	New	BIB/Orbera/Orbera365 Intragastic Balloon Systems	5/1/2018	Apollo Endosurgery Inc.	Al-Nozha Medical Est	FSN	https://nc
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	New	Biomet Hip System	4/30/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca
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	New	Cascadia Interbody System	5/1/2018	K2M Inc.	Bio Standards	FSN	https
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Hinge Coupling Hoffmann LRF	4/30/2018	Stryker Europe	Al-Faisaliah Medical System	2	https
New	Linx Reflux Management System	5/1/2018	Torax Medical	N/A	FSN	https
New	Nitinol Staples Elastic Staples - Large and Small Symmetrical	4/30/2018	TriMed Ortho	N/A	2	https://nc.mdr
New	SHERIC bipolar cup- Size 56/28	5/1/2018	Amplitude GmbH	N/A	FSN	https
New	WHIPKNOT Soft Tissue Cinch	4/30/2018	Smith & Nephew inc	Smith & Nephew inc	2	https

Ophthalmic and optical devices

New	CLARUS 500	5/1/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	A/CaV
New	Widefield OCT software	4/30/2018	DELBERG ENGINEERING Gr	Services & Health Care C	2	A/CaV

Reusable devices

New	Aequalis Humeral Nail Drill Bit ,	4/30/2018	Wright Medical Technology ,Inc..	Arabian Health Care Supply Co. (AHCSC)	2	https
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Single-use devices

New	Askina Calgitrol Paste, Askina Gel	4/30/2018	B Braun Medical Inc	Medical supplies & Services Co.Ltd	FSN	https
New	DeRoyal(R) SURGI MATE(R) Electrosurgical Pencil, Button Switch	5/3/2018	DeRoyal Industries Inc.	Alhaya medical co.	2	https://nc
New	Evicel Accessory Device	4/30/2018	Ethicon Inc.	Johnson Medical Saudi Ar	2	A/CaV
New	Medicina Nasogastric Tubes	4/30/2018	Medicina	Al Hammad Medical Services	2	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	NovaLine / Tubing Sets for Hemodialysis	5/1/2018	Vital Healthcare Sdn.Bhd.	Baxter AG	FSN	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.