



SBED Weekly Update

15-May-18

Dear,

SBED team is pleased to inform you that **46** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/7/2018 to 5/13/2018
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

Update	INGEVITY MRI extendable/retractable (active fixation) pacing lead	5/10/2018	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr
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New	Medtronic HeartWare™ HVAD™ System	5/9/2018	HeartWare Inc.	Medtronic Saudi Arabia	FSN	https://nc.mdr
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Anaesthetic and respiratory devices

New	Aluminum Dewars	5/13/2018	Chart Inc.	N/A	FSN	https://nc.mdr
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New	Nitrous Oxide/Oxygen Analgesic Gas Mixing and Delivery System	5/9/2018	O-Two Medical Technologies, Inc	Dar Al Najat Medical Tech.	2	https://nc.mdr
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Assistive products for persons with disability

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Nanosil Spray Gel	5/7/2018	Conseal International, Inc.	N/A	2	A/CaV

Dental devices

New	Straumann Emdogain	5/9/2018	Strumann Manufacturing, Inc.	Mar Al Jazirah Healthcare	2	A/CaV
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Diagnostic and therapeutic radiation devices


New	ARTIS pheno systems..	5/10/2018	SIEMENS	Siemens Medical Solution	FSN	A/CaV
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New	Artis zee/Q/Q.zen systems with Large Display DSC 5608-DC	5/10/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc
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New	MiroCam Capsule Endoscope System	5/7/2018	IntroMedic Co., Ltd..	Medical supplies & Services Co.Ltd	2	https
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New	Syngo Plaza	5/9/2018	Siemens Medical Solutions	Siemens Medical Solution	2	A/CaV
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Electro mechanical medical devices

#	New	3T Heater-Cooler Devices	5/7/2018	LivaNova PLC	cigalah group	2	Attac	
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#	New	Clip Gun Magazines	5/7/2018	Medtronic SA	Medtronic Saudi Arabia	2	ttache	
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#	New	EXACTAMIX Inlets	5/7/2018	Baxter Healthcare	Baxter AG	2	ttache	
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New	IntelliVue MX40	5/7/2018	Philips Healthcare	Philips Healthcare Saudi Arabia	FSN	A/CaV
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New	LIFEPAK® 15 and LIFEPAK® 12 with End-Tidal CO2 option	5/9/2018	Physio Control Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
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New	OmniDiagnost-Eleva and OmniDiagnost-Classic	5/7/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https
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New	PODOLOG MOON PROFESSIONAL	5/13/2018	HELLMUT RUCK GmbH	N/A	FSN	https
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	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Prismaflex Control Units	5/7/2018	Baxter Healthcare	Baxter AG	2	Attac

In vitro diagnostic devices

New	ABL9 sensor cassette	5/13/2018	Radiometer Medical	Salehiya Trading Est.	FSN	A/Ca\
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New	ADVIA Centaur CA 125II Assay	5/9/2018	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros.	2	Attac
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New	ADVIA Centaur®, ADVIA Centaur®XP, ADVIA Centaur®XPT, and ADVIA Centaur®CP	5/13/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr
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New	cMYC (MYC) Breakapart	5/10/2018	CYTOCELL LTD	awi Establishment for Me	FSN	A/Ca\
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New	Dimension® clinical chemistry system and Dimension Vista® System, Alkaline Phosphatase Calibrator (ALPI CAL)	5/7/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr.sfda.gov.s
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#	New	MicroVue CIC-C1q EIA and SC5b-9 Plus EIA Kits	5/7/2018	Diagnostic Hybrids Inc	N/A	2	Attac
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New	NeoBase Succinylacetone Assay Solution	5/7/2018	PerkinElmer Life and Analytical Sciences	ABDULREHMAN AL GOSAIBI GTB	2	https
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New	OXOID AST DISC CT0159B – Oxacillin OX1	5/9/2018	Oxoid Ltd Div Thermo Fisher Scientific Inc	Medical supplies & Services Co.Ltd	2	https
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New	PATHFAST CKMB, Myoglobin and NTproBNP	5/10/2018	Lsi Medience Corporation	Alinfrad Trading Est.	FSN	https://nc
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Non-active implantable devices

#	New	8 x 25 mm PLGA Full Thread Gentle Threads Interference Screws	5/8/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Cardica C-Port xA & Flex-A PLUS Anastomosis	5/10/2018	AesDex, LLC	N/A	FSN	https://nc.mdr
New	GII Tibial Punch .	5/13/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	A/Ca\
# Update	Mako Onlay Insert Extractor	5/9/2018	Stryker Orthopaedics	Zimmo Trading Establishment.	FSN	Attac
New	microTargeting Depth Stop Adapter	5/13/2018	FHC Inc...	Al Amin Medical Instruments Co. Ltd.	FSN	https
New	Sharp Curved Osteotome	5/10/2018	DePuy Ireland UC	Johnson Medical Saudi Ar	2	A/Ca\


Reusable devices

New	ReNew brand Disposable Scissor and Dissector Tips	5/10/2018	Microline Surgical Inc	Dawha Medical	2	https
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Single-use devices

New	All Arterial Cannulae and Customized Tubing Packs including the 3/8" Vent plug	5/10/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	https://nc.mdr
New	Centeze Centesis Catheter	5/13/2018	Galt Medical Corp	N/A	FSN	A/Ca\
New	Covidien Endo GIA™ Articulating Loading Units	5/7/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https
New	Custom Tubing Pack with Bioline Coating.	5/10/2018	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	2	https
New	Easyflex PVC empty bags	5/10/2018	Macopharma SAS	Dar ALKarmel	FSN	A/Ca\
New	HARMONIC ACE + Shears with Adaptive Tissue Technology	5/9/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	1	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	LYNDA + Amplya Acute Multitherapeutic System and CPFA Coupled Plasma Filtration Adsorption therapy	5/10/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https://ncmdr.sfda.gov.sa
# New	Medtronic Covidien Shiley Adult Flexible Tracheostomy Tubes	5/7/2018	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	2	Attached
# New	Needle Counters ,	5/7/2018	Medline Industries Inc	Thimar Al Jazirah Healthcare	2	Attached
New	PICC Insertion Tray	5/9/2018	Vygon UK Ltd	Thimar Al Jazirah Healthcare	2	A/Ca
New	SAM XT Extremity Tourniquet	5/13/2018	SAM Medical Products	Dallah Healthcare Company	FSN	https://ncmdr.sfda.gov.sa
New	Yankauer Suction Tubing, Penrose Tubing, Trocar Catheter, Thoracic Catheter	5/10/2018	Cardinal Health..	Medical Technology Establishment	FSN	https://ncmdr.sfda.gov.sa

- * 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.