



SBED Weekly Update 03-Apr-18

Dear,
SBED team is pleased to inform you that **70** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 3/26/2018 to 4/1/2018
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	Tec 7 Vaporizer, Aisys CS2 Aladin Cassette	3/28/2018	GE Healthcare	GE Healthcare	2	https://nc
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Update	Terumo Advanced Perfusion System 1 - Heart-Lung Machine.	3/29/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc mdr.
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Complementary therapy devices

New	Rotating IV Pole	3/28/2018	Ohmeda Medical	N/A	2	A/Ca\
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Dental devices

New	17° Multi-Unit Abutment Conical Connection NP 2.5mm	3/26/2018	Nobel Biocare Services AB	Medical Regulations Gate	FSN	https://nc mdr.
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	simplyInterActive Implant 5.0mmD x 10mmL SBM: 3.4mmD Platform	3/28/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	FSN	https://nc.mdr

Diagnostic and therapeutic radiation devices

New	BU IGT Systems, MultiDiagnost-Eleva	3/29/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc
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# Update	Integra CUSA Clarity Footswitch packaged with CUSA Clarity Console (Ref C7000	4/1/2018	Integra LifeSciences	Bio Standards	FSN	
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New	LOGIQ 9, LOGIQ E9, Vivid 7, Vivid E7, Vivid E9, Vivid E80, Vivid E90, and Vivid E95	3/26/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr.sfda
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New	SOMATOM GO.UP and SOMATOM go.Now..	4/1/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc
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New	Syngo.via software	4/1/2018	Siemens Medical Solutions	Siemens Medical Solution:	2	A/Ca
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New	TCM modules: TCM4 Combi, TCM CombiM and TCM Tosca	4/1/2018	Radiometer America Inc	Salehiya Trading Est.	FSN	https://nc.mdr
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Electro mechanical medical devices

New	ARROW ENDURANCE" Extended Dwell Peripheral Catheter System	4/1/2018	Arrow International Inc	Gulf Medical Co.	2	https://nc.mdr.sfda
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New	ARROW, ARROWGARD AND ARROWGARD BLUE PLUS PRESSURE INJECTABLE CENTRAL VENOUS CATHETER	3/26/2018	Arrow International Inc	Gulf Medical Co.	2	https://nc.mdr.sfda.gov.s
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New	BetterBladder	3/26/2018	Circulatory Technology Inc	N/A	2	A/Ca
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	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	Update	da Vinci X Patient Side Cart Arm Controller Joint Circuit Boards	3/29/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	
	New	Entroy	3/28/2018	Arjo Huntleigh	I-Faisaliah Medical Syster	FSN	A/Ca\
	New	First Step Flexible Endoscope Bedside PreClean Kit, EP4.	3/28/2018	Madison Polymeric Engineering	N/A	2	https://nc.mdr.
	New	HEMASHIELD Knitted Double Velour Cardiovascular Fabric	3/26/2018	Maquet Cardiovascular,LLC.	Saudi Sicli Company	2	https://nc.mdr.
#	New	Medfusion 3010 and 301A Syringe Infusion Pumps .	3/29/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	
	New	OTESUS OR table	3/26/2018	MAQUET Inc	Gulf Medical Co.	FSN	A/Ca\
	New	PadPro MiniInfant Multifunction Electrodes 2602 Series	3/27/2018	ConMed Corporation.	ProMedEx	2	https://nc.mdr.
	New	Rythmic Evolution	3/28/2018	Micrel Medical Devices S.A	chno-Orbits Establishme	FSN	A/Ca\
	New	Syramed μSP6000 and Volved μVP7000 .	3/28/2018	Arcomed AG	Al-Faisaliah Medical System	FSN	https://nc.
#	New	Trumpf Medical T3 Spinal Tabletop Systems	3/26/2018	Allen Medical Systems	Reem Alwasat for Trading Company.	2	


Healthcare facility products and adaptations

	New	Getinge Sterilizer ,	4/1/2018	Getinge Disinfection AB	Gulf Medical Co.	2	A/Ca\
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Hospital hardware


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
Update	IMRIS ORT100 and ORT300 Operating Room Tables	4/1/2018	Deerfield Imaging	Gulf Medical Co.	2	https://nc.mdr


New	IMRIS ORT300 Removable Operating Room Table	4/1/2018	Deerfield Imaging	Gulf Medical Co.	2	https://nc.mdr
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#	New	Model 6390 Power-LOAD Cot Fasteners	3/29/2018	Stryker	Al-Jeel Medical & Trading Co. LTD	2		
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In vitro diagnostic devices

#	New	0.8% Surgiscreen Reagent Red Blood Cells	3/29/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2		
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#	New	32 mg/L AUGMENTIN Plates	4/1/2018	MAST International Ltd	Al Nahir Trading Co	2		
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#	Update	Artisan Link and LinkPro Automated Slide Stainers	4/1/2018	Agilent Technologies, Inc.	N/A	2		
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New	Atellica COAG 360.	3/28/2018	s Healthcare Diagnostics F	AL-KAMAL Import	FSN	A/Ca
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New	AutoMate 2500 Family	3/26/2018	Beckman Coulter...	an Coulter Saudi Arabia C	2	A/Ca
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New	BD Vacutainer EDTA Tubes	3/26/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	https://nc
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New	cobas c 6000 MODULAR Series System e 601	4/1/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	https://nc
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#	New	Common Diabetes Kits, No Spiro Kits, No Spiro Diabetes Kits and Common Kits	3/26/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2		
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New	CP3000 System	3/28/2018	Sekisui Diagnostics	pplies & Services Co.Ltd	FSN	A/Ca
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#	New	Dimension Vista Drug of Abuse Controls ,	4/1/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
	New	HbA1c HIT917	4/1/2018	on diagnostic concepts Gr	N/A	FSN	A/Ca\
	New	iQ200 Series Urine Microscopy Analyzer	3/28/2018	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
	New	onal Mouse, Anti-Pneumocystis J. & Anti Human	4/1/2018	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	FSN	https://nc mdr.
	New	PERSONA THE PERSONALIZED KNEE SYSTEM...	4/1/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc mdr.
	New	Sofia 2	3/28/2018	Quidel Corporation	A FOUAD HOLDING COM	2	A/Ca\
	New	Thermo Scientific Oxoid Mueller-Hinton Broth.	3/26/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd	FSN	https://nc
	New	VIDAS FSH	3/28/2018	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca\
	New	VIKIA Malaria Ag Pf/Pan	4/1/2018	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca\

Non-active implantable devices

	New	AltiVate Reverse, HUMERAL SOCKET SHELL TRIAL, STANDARD	4/1/2018	Encore Medical, Lp	AL EWAN MEDICAL COMPANY	2	https://nc mdr.
	Update	Autoplex and Hivac Cement Inject	4/1/2018	Stryker Instruments.	Zimmo Trading Establishment.	FSN	https://nc
	New	BeGraft Peripheral Stent Graft System.	3/28/2018	Bentley InnoMed GmbH	Ameesa Medical Instruments	FSN	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Charcot Osteotome Chisel (Trauma & Foot and Ankle instruments)	3/26/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https://nc.mdr
New	Comprehensive Segmental Revision System	3/27/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc.mdr
New	Epoca Stem Extractors and Connection Screws	4/1/2018	Synthes GmbH.	Johnson & Johnson Medical Saudi Arabia	FSN	https://nc
New	FLEX ARM INSTRUMENT	4/1/2018	Synthes GmbH.	Johnson Medical Saudi Ar	FSN	A/Ca
New	Phoenix Nail System	4/1/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca
New	REVITAN prox. spout 75	3/26/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	A/Ca
New	Torque Limiter 10Nm, Org.	3/26/2018	Silony Medical	Saudi Imas Company For Medical Products	FSN	https://nc

Ophthalmic and optical devices

New	Spot Vision Screener 100	4/1/2018	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	2	https://nc
New	StoneBreaker Pneumatic Lithotripter	4/1/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	FSN	https://nc

Reusable devices

New	GETINGE Aperlan Poka-Yoke Agent A	3/26/2018	Getinge Disinfection AB	Gulf Medical Co.	FSN	https://nc
New	TANZO TOUCH TT+23	3/26/2018	on Medical Instrument Co.	marketing and trading cor	FSN	A/Ca


Single-use devices

#	Update	Dialysate Sacks	3/27/2018	NxStage Medical, Inc.	DWAN MEDICAL SERVIC	2	!
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	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	First Step Kits, Draco Enzymatic Deep Cleaning Pads, 4-Inch Button Brushes and Travel Kits	3/29/2018	Cygnus Medical LLC	N/A	2	
#	Update	Intro-Flex Automatic Hemostasis Valve Introducer	4/1/2018	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	
	New	LIFE 18 - Theraline pro Tubing set	3/26/2018	Miltenyi Biotec GmbH	Enjaz Medical Modern Company	FSN	https://nc
	New	MICROPLAS plasmafilters	4/1/2018	Bellco Canada	Medtronic Saudi Arabia	FSN	A/Ca
	New	Mölnlycke Procedure trays, Cannula Needle, 100mm, 18G	3/26/2018	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	https://nc.mdr
	New	Multi-lumen Altius Central Venous Catheter kit	4/1/2018	Kimal Plc.	First Medical co. Ltd.	FSN	https://nc.mdr
#	New	Nasogastric Sump Tubes with ENFit Connector	3/29/2018	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	
	Update	Norm-Ject Tuberkulin Syringes	3/28/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	2	https://nc
	New	TRO-DONORSET	3/26/2018	Troge Medical GmbH	ullah Baghaffar Sons Co.,	FSN	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.