



SBED Weekly Update 05-Dec-17

Dear,

SBED team is pleased to inform you that **52** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/28/2017 to 12/3/2017
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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Anaesthetic and respiratory devices

New	Computer Assisted Surgical Device.	11/30/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https
New	ComputerAssisted Surgical Device.,	11/30/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https
New	Rechargeable Li-Ion Batteries with incorrect firmware used in Puritan Bennett 980 Ventilators	11/30/2017	Medtronic SA	Medtronic Saudi Arabia	2	https://nc.mdr.
New	ROSA Spine 1.0.2	11/30/2017	Zimmer Biomet	in Medical Instruments C	2	A/Ca\
# New	Southmedic ETCO2 OxyMask Oxygen Masks	11/29/2017	Vyaire Medical	N/A	2	Attac

Assistive products for persons with disability

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Molnlycke Sundance Solutions Z-Flo Fluidized Positioners	12/3/2017	Medline Industries Inc...	Ikar Establishment	2	Attac hed
New	Wheelchair models Skater, Trend, Jump alpha/ beta, Vector	11/28/2017	SORG Rollstuhltechnik	N/A	FSN	https://nc

Dental devices

New	Various Dental Products	11/28/2017	Zimmer inc	m M. Al-Mana & Bros. C	FSN	A/CaV
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Diagnostic and therapeutic radiation devices

New	BRAINLAB EXACTRAC VERO	11/30/2017	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	2	https
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# New	CosyCrib Neonatal Nursing Systems	11/30/2017	Inspiration Healthcare Group PLC	Alwiam Medical Company	2	Attac hed
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Update	Integrity 1.2	11/30/2017	Software Systems IMPAC	Medical Regulations Gate	FSN	A/CaV
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# New	IntelliSpace Cardiovascular and Xcelera Systems	11/30/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attac hed
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New	Millennium VG, Discovery VH, VariCam	11/28/2017	GE Healthcare	GE Healthcare	FSN	https
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# New	Model 8110 Alaris Syringe and Model 8120 Alaris PCA Modules	11/30/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	2	Attac hed
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# New	Presource Kits Containing Skytron/Ecolab Disposable Camera Covers	11/30/2017	Cardinal Health..	Medical Technology Establishment	2	Attac hed
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New	RayStation and RayPlan	12/3/2017	RaySearch Laboratories AE	N/A	2	A/CaV
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	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Spot Vision Screener 100 Devices	11/29/2017	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	2	Attac
	New	TomoTherapy Treatment System.	11/30/2017	Accuray Inc	Gulf Medical Co.	FSN	https

Electro mechanical medical devices

#	New	LUCAS 2 Chest Compression Systems	11/30/2017	Physio Control Inc	Al-Jeel Medical & Trading Co. LTD	2	Attac
#	New	PureFlow-B Solution .	11/30/2017	NxStage Medical, Inc.	DWAN MEDICAL SERVIC	2	ttache

In vitro diagnostic devices

	New	Antistreptolysin O FS	11/28/2017	ys Diagnostic Systems Gr	Ghuyum Scientific Tradir	FSN	A/Ca
	New	Atellica 1500 Automated Urine Sediment Analyser	11/30/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros.	FSN	https
	New	Atellica COAG 360	11/28/2017	Siemens Healthcare Diagnos	Ibrahim Batterjee & Bros	FSN	A/Ca
#	New	DCA Vantage Analyzer and CLINITEK Status Connect System Handheld Barcode Reader Kits	11/30/2017	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	2	Attac hed
	New	DI-60, CellaVision DM96, CellaVision DM1200, CellaVision DM9600	11/28/2017	CellaVision AB	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc
	New	Epiclone Anti-M Blood Grouping Reagent	11/30/2017	Seqirus Pty Ltd	N/A	2	https
	New	Epiclone Anti-M Blood Grouping Reagent.	11/30/2017	Seqirus Pty Ltd	N/A	2	https
	New	Foetal Haemoglobin Monoclonal Antibody (HBF-1).	11/30/2017	Life Technologies Limited.	Integrated Gulfbiosystems	2	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	gabControl Spice Test	11/28/2017	gabmed	N/A	FSN	A/CaV
New	Humatex ASO	11/30/2017	haft für Biochemica und D	N/A	FSN	A/CaV
New	iChem VELOCITY Chemistry Strips	11/28/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https
New	Measles IgM ELISA	11/28/2017	ROTECH Diagnostics Gmb	N/A	FSN	A/CaV

Medical software

New	IntelePACS with software versions 4-3-1 and up	12/3/2017	Intelerad Medical Systems Inc..	N/A	2	https
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Non-active implantable devices

New	Autoplex and Hivac Cement Inject	11/30/2017	Stryker Instruments.	Zimmo Trading Establishment.	FSN	https	
New	Cardioband Mitral Reconstruction System	11/30/2017	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	FSN	https	
#	New	GENERIC Femoral Stems	11/29/2017	Amplitude GmbH	N/A	2	ttache
New	Lifeseal Surgical Sealant	11/28/2017	duomed	N/A	FSN	A/CaV	
New	METS Principal Shaft	11/30/2017	er Howmedica Osteonics	nmo Trading Establishme	2	A/CaV	
#	New	METS Principal Shafts	11/29/2017	more Implants Worldwide	nmo Trading Establishme	2	ttache

Ophthalmic and optical devices

#	New	Beaver Xstar Safety Knives	11/30/2017	aver Visitec International I	in Medical Instruments C	2	ttache
New	Pentacam AXL	11/28/2017	CULUS Optik Geräte Gmb	N/A	FSN	A/CaV	

Reusable devices


#	New	First Step EP-4 Pouches	11/29/2017	Cygnus Medical LLC	N/A	2	ttache
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Spectra System/Legacy Guided Surgery Handle Kit Inserts	11/30/2017	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	2	https://nc

Single-use devices

#	New	5 mm Unifine Pentips Pen Needles	11/29/2017	Owen Mumford	Medical supplies & Services Co.Ltd	2	Attac	
	New	BARRIER Ultimate Surgical Gown	11/28/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	https	
#	New	Freka Intestinal Tubes	11/30/2017	Fresenius Kabi AG	Alhaya medical co.	2	ttache	
	New	Global Cup Poly Liner, Neutral prostheses	11/30/2017	Global Manufacturing Technology	N/A	2	https	
#	New	Kits Containing Medline Aplicare Povidone Iodine Prep Pads	11/30/2017	BUSSE HOSPITAL DISPOSABLES.	Teriag International	2	Attac hed	
#	New	Microdot Droplet Pen Needles	11/29/2017	HTL-STREFA SA	N/A	2	Attac	
	New	RUSCH SENSOR 2 WAY SILICONE CATHETER, STERILE	11/30/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https://nc	
	New	RÜSCH PVC catheter Tiemann pattern	11/28/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	https	
#	New	Various Disposable Products	11/30/2017	Stryker Endoscopy	Al-Faisaliah Medical System	2	Attac	

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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.