



SBED Weekly Update 17-Oct-17

Dear,
SBED team is pleased to inform you that **23** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/9/2017 to 10/15/2017
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	Distributor	Class	Link
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Active Implantable Devices

Update	Fortify, Fortify Assura, Quadra Assura, Quadra Assura MP, Unify, Unify Assura and Unify Quadra	10/12/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr
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Anaesthetic and respiratory devices

New	Carestation 620, 650 and 650c - Potential for Elevated FiCO2	10/12/2017	GE Medical Systems	GE Healthcare	FSN	https://nc
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Assistive products for persons with disability

New	PRISM MEDICAL A625	10/9/2017	Handicare Ltd	Al Safwa Dimensions	2	A/Ca\
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Diagnostic and therapeutic radiation devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Brilliance 64, Ingenuity Core, Ingenuity Core 128, Ingenuity CT	10/12/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc
New	Dual Hemo MCable pod used with the Infinity Acute Care System (IACS) Monitoring Solution	10/9/2017	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	https://nc.mdr.
New	MAKO PKA & THA software of RIO system (MAKO Robot)	10/9/2017	Stryker Orthopaedics	Zimmo Trading Establishment.	FSN	https://nc
New	MAQUET HLX 2004-5 DF, HLX 3004-5 DF and XTEN DF	10/12/2017	Getinge Disinfection AB	Gulf Medical Co.	FSN	https://nc

Electro mechanical medical devices

#	Update	Auriga XL 4007 Laser System ,	10/9/2017	Boston Scientific	Gulf Medical Co.	2	Attac
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In vitro diagnostic devices

	New	Fluorocell PLT reagent.	10/12/2017	Sysmex America Inc	MAAMOUN TAMER & C	2	A/CaV
	Update	NucliSENS Lysis Buffer	10/12/2017	bioMerieux Inc	el Medical & Trading Co.	2	A/CaV
	New	S. AIA-PACK PROG II and S. AIA-PACK PROG III	10/10/2017	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	FSN	https








Non-active implantable devices

#	New	Antegrade Femoral Connecting Bolts	10/10/2017	Zimmer, INC....	Medical Regulations Gate	2	Attac
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Reusable devices

#	New	Pilling Knife Handles	10/9/2017	Teleflex Medical	im M. Al-Mana & Bros. C	2	ttache
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Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Aplicare Povidone Iodine Prep Pads	10/9/2017	Medline Industries Inc...	Ikar Establishment	2	Attac 
#	New	19 Fr Silicone Hubless Round Channel Drains	10/9/2017	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	Attac 
#	New	Aplicare Povidone Iodine Prep Pads Contained in IV Start Kits ,	10/15/2017	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	2	Attac hed 
	New	ARS Decompression Needle	10/9/2017	North American Rescue	N/A	FSN	https
#	New	BD 3 mL ChloroPrep with Tint Contained in Medline Kits	10/9/2017	Medline Industries Inc...	Ikar Establishment	2	Attac hed 
	New	Phaseal Secondary Set (C61)	10/12/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	https
#	New	Reinforced Dual-Lumen ECMO Catheters	10/9/2017	OriGen Biomedical	Arabian Trade House Est.	1	Attac 
#	New	Smiths 15 mL Unit Dose Normal Saline Vial Components Included in Closed Suction Systems for Adults	10/15/2017	Halyard Health Co.	Arabian Health Care Supply Co. (AHCSC)	2	Attac hed 
#	New	Synergy Health Maternity Pads Contained in Procedure Trays	10/9/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	2	Attac hed 
	New	Various Disposable Catheter Mounts,	10/10/2017	MEDIPLAST AB	Eylaf Medical Trading Est.	1	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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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.