



SBED Weekly Update 14-Nov-17

Dear,
SBED team is pleased to inform you that **28** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/6/2017 to 11/12/2017
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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Active Implantable Devices

New	CP5 CENTRIFUGAL PUMP	11/12/2017	LivaNova PLC	cigalah group	FSN	A/Ca\
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Dental devices

New	2.5 mm GemLock Hex Driver, RHD2.5	11/8/2017	Zimmer, INC....	Medical Regulations Gate	FSN	https://nc
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Diagnostic and therapeutic radiation devices

New	Agility 3.2	11/8/2017	Software Systems IMPAC I	Medical Regulations Gate	FSN	A/Ca\
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#	New	Endoflator Tubing with Filter	11/6/2017	Karl Storz GmbH & Co KG	Gulf Medical Co.	2	Attac hed
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New	ExacTrac Vero	11/8/2017	BrainLAB	el Medical & Trading Co.	FSN	A/Ca\
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New	Flex Cardio Patient Monitoring System	11/12/2017	Invivo Corporation	N/A	2	https://nc
New	Integrity 1.2	11/8/2017	Software Systems IMPAC I	Medical Regulations Gate	FSN	A/Ca

Electro mechanical medical devices

New	9195371DS Lithotripsy Probe LotLDS12516	11/12/2017	Northgate	N/A	2	https://nc
New	FlexFlow™ venous cannula Catalog 200200	11/12/2017	Sorin Group	Arabian Trade House Est.	2	https://nc

In vitro diagnostic devices

New	Bond Aspirating Probe Cleaning System	11/8/2017	Leica Microsystems, Inc.	Salehiya Trading Est.	FSN	https://nc
New	Dimension® and Dimension Vista® Assays Biotin Interference	11/8/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc mdr
New	Epi proColon Plasma Quick Kit	11/8/2017	Epigenomics AG	N/A	FSN	https://nc
# Update	FLEX Monoclonal Rabbit Anti-Human Estrogen Receptor Clone EP1, Ready-to-use	11/6/2017	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	1	Attached
New	Remel Vibrio cholerae Inaba Agglutinating Serum.	11/8/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc mdr
Update	software Kapelan LabImage LA	11/8/2017	VIROTECH Diagnostics GmbH	N/A	FSN	https://nc
New	ZENIT RA Scl-70 REF. 41418	11/8/2017	Technogenetics s.r.l.	N/A	FSN	https://nc

Medical software

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Custom surgical kits	11/12/2017	Bioseal Corporation	N/A	2	A/CA\

Non-active implantable devices

New	Custom Ti MAK RS OSS Segmental Femoral Rotating Hinged Knee	11/12/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https://ncmdr
New	Cobalt HV Bone Cement..	11/12/2017	Encore Medical, Lp	El Ewan Medical Company	2	A/CA\
New	COLUMBUS REV FEMUR SPACER DISTAL F5 15MM	11/8/2017	Aesculap	Gulf Medical Co.	FSN	https://nc
New	Eluvia 150mm and Innova 180mm & 200mm Stent Systems	11/8/2017	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://ncmdr
New	HEMOSNOW, COVA+, MATRIBONE	11/12/2017	Biom'up	N/A	FSN	https://nc
New	T&A Pack	11/12/2017	Istone Medical Packaging,	Gulf Medical Co.	2	A/CA\


Reusable devices

#	New	OCS Heart Perfusion Modules	11/6/2017	TransMedics	N/A	2	Attached
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Single-use devices

New	DORO® Sterile Disposable Skull Pins	11/6/2017	Pro Med Instruments GmbH	Al Amin Medical Instruments Co. Ltd.	FSN	https://nc
New	MYO/Punch, A&E Surgical Punch	11/12/2017	A&E Medical Corporation	N/A	FSN	https://nc
New	Nasogastric Feeding Tubes for neonates & pediatric	11/8/2017	Maxter Catheters	Reem Alwasat for Trading Company.	FSN	https://ncmdr
Update	Tuohy Epidural Needles	11/12/2017	Epimed International Inc	Pioneer Medical Company	2	A/CA\

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.