



SBED Weekly Update

10-Jul-17

Dear,

SBED team is pleased to inform you that **37** new FSCA/recalls posted on [SFDA website](#)

(Please note: below list of FSCA/ recalls for the period of 7/3/2017 to 7/9/2017

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	A-Series Anesthesia Systems	7/7/2017	Shenzhen Mindray	Salehiya Trading Est.	FSN	Attac hed
#	New	BVM Manual Manual Resuscitation Systems	7/7/2017	Intersurgical Limited	Al Hammad Medical Services	2	https://nc

Assistive products for persons with disability

New	Pivot, Pivot Hygiene, Pivot Hammock and Tony Pringle clip style sling with the keyhole clip fastening	7/9/2017	Nortec NZ	N/A	2	https://nc.mdr.sfda.gov.s
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Dental devices


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Drew Scientific DREW 3-PAC Reagent Kit containing: 5L Diluent, 750 mL Enzymatic Cleaner, and 125 mL Lysing Reagent.	7/6/2017	JAS Diagnostics Inc.(subsidiary of ERBA Diagnostics).	N/A	2	https://ncmdr.sfda.gov.sa/Se

Diagnostic and therapeutic radiation devices

New	IMPAX Cardiovascular	7/6/2017	AGFA Corp.	Gulf Medical Co.	2	A/Cal
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New	MOSAIQ Systems ,	7/3/2017	MPAC Medical Systems In	Medical Regulations Gate	FSN	A/Cal
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New	Proteus 235 and Proteus ONE proton therapy systems	7/6/2017	Ion Beam Applications S.A.	N/A	2	https://ncmdr
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# New	Vibe Sensis Systems	7/7/2017	SIEMENS	iemens Medical Solution	2	ttache 
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Electro mechanical medical devices

New	3M Ranger(TM) Pressure Infusor	7/5/2017	3M Health Care Ltd	3M company	2	https://nc
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New	Hand Foot II ,	7/3/2017	National Biological Corp	n Medical Instruments C	FSN	A/Cal
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# Update	MiniMed 640G Insulin Infusion Pump..	7/7/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	
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# New	Plum 360 Infusion Systems	7/9/2017	ICU Medical, Inc	AL-KAMAL Import	2	https://nc
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Update	Prismaflex System, Prismaflex 4.11, Prismaflex 5.00 Row, Prismaflex 6.10 Row and Prismaflex 7.XX Row.	7/3/2017	Baxter Healthcare	Baxter AG	FSN	https://ncmdr.sfda.gov.s
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Sealing Caps (A0282 and A0313) used with compatible endoscopy instruments	7/9/2017	Olympus	Salehiya Trading Est.	2	https://ncmdr.sfda
New	TI Transport Monitor/Module Battery Pack	7/5/2017	Shenzhen Mindray	Salehiya Trading Est.	2	https://ncmdr

In vitro diagnostic devices

New	ARCHITECT c4000 Cuvette Segment	7/3/2017	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd	FSN	https://nc
New	BacT/ALERT BPN Culture Bottles	7/9/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc
New	BK Virus R-gene Real-time Detection and Quantification Kit.	7/9/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://ncmdr
# New	COULTER LH and HmX Analyzers	7/6/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	https://nc
New	Haemophilus Test medium (HTM).	7/9/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc
New	MULTIGENT Quinidine	7/3/2017	poration, part of Thermo	pplies & Services Co.Ltd	FSN	A/CA
New	Pre-Transfusion Blood Testing System PK7300 Automated Microplate System	7/9/2017	Beckman Coulter UK Ltd	Beckmancoulter INT L	2	https://ncmdr.sfda
New	Recapper for the AutoMate 2500 Family.	7/9/2017	Beckman Coulter UK Ltd	Beckmancoulter INT L	2	https://nc
New	Sysmex CA-600 series with built-in barcode reader.	7/9/2017	Sysmex Europe GmbH..	AL-KAMAL Import	2	https://ncmdr

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Symex XN-450, XN-550 & other XN-L series Automated Haematology Analysers	7/9/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	https://ncmdr.sfda
New	VIDAS Testosterone	7/6/2017	bioMerieux Inc	el Medical & Trading Co.	2	A/Ca\

Non-active implantable devices

New	BioGlue Surgical Adhesive,	7/5/2017	CryoLife, Inc.	Almarfa Medical	2	https://nc
# New	Delta Ceramic Femoral Heads	7/7/2017	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	Attac hed 
New	ELEOS LIMB SALVAGE SYSTEM SEGMENTAL STEM	7/5/2017	Onkos	N/A	2	https://ncmdr
New	IVS Bone Cement	7/3/2017	Stryker Europe	I-Faisaliah Medical Syster	FSN	A/Ca\


Ophthalmic and optical devices

New	M720 + Protective Glass Holder	7/3/2017	Leica Microsystems Inc.	Al-Faisaliah Medical System	FSN	https://nc
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Reusable devices

New	AxiEMTM ENT Suction instruments	7/4/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
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Single-use devices

# New	25 G Orange Needles Contained in Ophthalmic Sterile Procedure Trays	7/7/2017	Medline Industries Inc...	Ikar Establishment	2	Attac hed 
New	Codan Extension Set with T Connector,	7/9/2017	CODAN Medizinische Geraete GmbH & Co KG	Alwan Alnoor Trading Est.	2	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Imager II Angiographic Catheter ,	7/5/2017	Boston Scientific Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	https://nc
New	Multiple Medtronic DLP products	7/4/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
# Update	Zenith Alpha Thoracic Endovascular Graft.	7/7/2017	William Cook Europe ApS	NAFA Medical	FSN	Attac hed

* 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.