



SBED Weekly Update

22-May-18

Dear,

SBED team is pleased to inform you that **38** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/14/2018 to 5/17/2018
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	Distrbutor	Class	Link
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Dental devices

New	Alpen Carbide 702 Cross Cut Tapered Fissure FG 10 pack	5/17/2018	Coltene Whaledent Inc.	Asnan est. for Medical Services	2	https://nc
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New	Jasper Vektor	5/14/2018	TP Orthodontics Inc.	N/A	2	A/Ca
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Diagnostic and therapeutic radiation devices



New	CEREC AC / AF / AI with Omnicam	5/14/2018	DENTSPLY International	Branch of DENTSPLY International Inc	FSN	https
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New	Hemodynamic Monitoring System	5/14/2018	ICU Medical, Inc	AL-KAMAL Import	2	https
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New	Monitor, Physiological, Patient (with Arrhythmia Detection or Alarms)	5/16/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	2	https://nc
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New	Monitoring Kit Transpac IT	5/17/2018	ICU Medical, Inc	AL-KAMAL Import	FSN	A/Cal
New	Ondamed Biofeedback Device	5/14/2018	Ondamed Inc	N/A	2	https
New	Syngo.Via VB20A model 1049610	5/14/2018	Siemens Medical Solutions	Siemens Medical Solutions	2	https
New	Trident Endoscopic Ultrasonic Aspiration Needle (FNA)	5/17/2018	Micro-Tech (Nanjing) Co., Ltd	Tayeb Medical Est	2	https
New	Vision C	5/14/2018	Visaris d.o.o.	N/A	FSN	A/Cal

Electro mechanical medical devices

New	Akron Tilt Table couches	5/17/2018	jo Huntleigh - electric bec	Gulf Medical Co.	FSN	A/Cal	
New	DriSate	5/16/2018	Rockwell Medical, Inc	N/A	2	A/Cal	
#	New	Model 1007CCV Thumper Cardiopulmonary Resuscitators	5/15/2018	Michigan Instruments	N/A	2	Attac hed 
#	New	Model 8100 Alaris Pump Modules.	5/15/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	Attac hed 
New	POWERPORT(R) ClearVUE®	5/14/2018	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	https	
New	SEEKER(R) Crossing Support Catheter	5/14/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	https	
New	WetField Hemostatic Eraser Bipolar 25G	5/14/2018	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	2	https	

Healthcare facility products and adaptations

New	Fischer Cone Biopsy Excisor	5/17/2018	CooperSurgical Inc..	ATTIEH MEDICO LTD	2	https
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In vitro diagnostic devices

New	Accu-Chek Inform II test	5/14/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	2	A/CaV
New	cobas m 511 integrated hematology analyzer	5/17/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc
New	CRP IS / Super ID CRP; TruLab CRP / Nobicon CRP by	5/14/2018	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	https://nc
New	FlexLab (FLX), Accelerator a3600 (ACP), Aptio Automation (AP2)	5/14/2018	Inpeco S.A.	Medical supplies & Services Co.Ltd Mediserv	2	https://nc
New	Tosoh ST AIAPACK HbA1c Calibrator	5/16/2018	Tosoh Bioscience Inc	N/A	2	https://nc
New	VITROS Chemistry Products PHYT Slides	5/14/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https://nc

Non-active implantable devices

New	Epic Extremity Plate System	5/17/2018	Epic Extremity, LLC	N/A	2	https://nc
New	Farabeuf Clamp for 3.5mm Screws PRO	5/16/2018	Stryker	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
New	Kelyniam CSI	5/16/2018	Kelyniam Global, Inc.	N/A	2	A/CaV
New	Medtronic ZEVO(TM) Anterior Cervical Plate System SLOT SCREW	5/14/2018	Medtronic SA	Medtronic Saudi Arabia	2	https://nc
New	Reprocessable surgical instruments	5/14/2018	Mattes Instrumente GmbH MedizinTechnik	Commercial & Maintenance Co. For	FSN	https://nc

Ophthalmic and optical devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Eyewash Stations and 32 Ounce Eyewash Station Refills	5/15/2018	Ecolab Inc..	Al Hammad Medical Services	1	Attac hed

New	NvisionVLE	5/14/2018	Ninepoint Medical Inc.	N/A	2	A/Ca\
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Reusable devices

New	Olympus EVIS DUODENOVideoscope PJF-240	5/14/2018	Olympus	Salehiya Trading Est.	FSN	https://nc
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Single-use devices

# New	atheter Convenience Sets Containing Teleflex Arrow Catheter Clamps with Fastener	5/15/2018	Prytime	N/A	1	Attac hed
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# New	CARDIOSAVE Intra-Aortic Balloon Pumps	5/15/2018	MAQUET Cardiovascular LLC	Al-Jeel Medical & Trading Co. LTD	1	Attac
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New	Convatec Esteem(TM) Synergy Stomahesive(R),	5/17/2018	ConvaTec	Salehiya Trading Est.	2	https
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New	Nipro Blood Tubing set with Priming Set and Transducer Protectors. Each device is packaged in a film	5/17/2018	Nipro Medical Corporation..	Spectromed	2	https://nc.mdr.sfda
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Update	Resuscitation Devices ,.	5/14/2018	Vyaire Medical	N/A	2	A/Ca\
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New	Sterile Aquasonic 100 Ultrasound Transmission Gel	5/14/2018	Parker Laboratories, Inc..	Majal Care for Trading Est.	2	https://nc
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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.