



SBED Weekly Update

07-Aug-18

Dear,

SBED team is pleased to inform you that **35** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/30/2018 to 8/5/2018
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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Active Implantable Devices

New	Final Pack, Esteem II, Sound Processor Model 2001	8/2/2018	Envoy Medical Corporation	N/A	2	https://nc	
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New	VNS Therapy Programming System	7/31/2018	LivaNova PLC	cigalah group	2	https	
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Anaesthetic and respiratory devices

New	Aurum Healthcare Tubing Systems	8/2/2018	AURUM HEALTHCARE SDN BHD	N/A	FSN	https	
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Diagnostic and therapeutic radiation devices

#	New	ARTIS Q and ARTIS Pheno Systems	8/5/2018	SIEMENS	Siemens Medical Solutions	2	Attac	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# New	BIS Vista and BIS View Monitoring Systems	8/5/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac	
# New	Brilliance iCT, Brilliance 16 Air, and Brilliance 64 Computed Tomography Systems	7/30/2018	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	2	Attached	
New	CDI Blood Parameter Monitoring System 500 H/Sat Probe Assembly	7/31/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	https://nc	
New	Sonolith i-move	8/2/2018	EDAP TMS FRANCE SAS,	Al-Zahrawi Medical Co.	FSN	A/Ca\	

Electro mechanical medical devices

New	Arrow Percutaneous Sheath Introducer Kit	8/1/2018	Arrow International Inc	Gulf Medical Co.	2	https	
# New	Beaver 2-Inch Shaft with Fine Tip Accu-Temp High-Temperature Cautery Devices	8/5/2018	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	2	Attached	
New	Cardiovascular Procedure Kit	7/31/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	https	
New	ETHICON Generator Gen11	8/2/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia	FSN	https	
New	HCU 40	8/2/2018	aqet Cardiopulmonary A	l-Faisaliah Medical Syster	FSN	A/Ca\	
Update	Natus NicoletOne 32Ch Ambulatory EEG Record System	7/31/2018	Natus Neurology	Medical supplies & Services Co.Ltd Mediserv	2	https://nc	
# New	Plum 360 Infusers	8/5/2018	ICU Medical, Inc	AL-KAMAL Import	2	ttache	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM	7/31/2018	DexCom Inc	Bio Standards	2	https://nc	

New	Thermablate EAS	8/2/2018	IDOMAN TEORANTA.	Medical Experts Company	FSN	A/Ca	
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Healthcare facility products and adaptations

# Update	VOLISTA STANOP, TRIPOD, ACCESS and QUICKLOCK Light heads	7/30/2018	MAQUET Inc	Gulf Medical Co.	2	Attac hed	
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New	V-PRO 1, V-PRO 1 Plus, and V-PRO maX Low Temperature Sterilization Systems	8/2/2018	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc mdr.	
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Hospital hardware

# New	Bariatric Drop End Couches	8/5/2018	SEERS MEDICAL LIMITED	Nahdi Medical Company	2	Attac	
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In vitro diagnostic devices

New	ADVIA Centaur CKMB Calibrator Bias and Out of Range Results Using Master Curve Material (MCM)	7/31/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc mdr. sfda.	
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New	antigen typing for vial 4	7/31/2018	Immucor GmbH.	ppplies & Services Co.Ltd	FSN	A/Ca	
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New	EZ1 Advanced XL	8/1/2018	QIAGEN Ltd	A FOUAD HOLDING CO	FSN	A/Ca	
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New	NanoZoomer S360	8/1/2018	Hamamatsu Corporation	N/A	FSN	A/Ca	
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New	NK012.S - Human IgM Kit for use on SPAPLUS	8/1/2018	The Binding Site	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https	
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New	recomWell Borrelia IgM	8/1/2018	Mikrogen GmbH	WAREED ALHAYAT	FSN	A/Ca	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	STA Néoplastine CI 10 and CI Plus 10	8/1/2018	Diagnostica Stago	Medical supplies & Services Co.Ltd	FSN	https://nc.mdr	
New	VITROS Chemistry Products CI- Slides & VITROS Chemistry Products CREA Slides	8/5/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https://nc.mdr	
New	Xpert C.Difficile BT assay	8/1/2018	Cepheid	A FOUAD HOLDING CO	FSN	A/Ca	
New	Yumizen H2500 & H2500 SPS	8/2/2018	HORIBA ABX SAS.	Samir Photographic Supplies Co. Ltd.	FSN	https://nc.mdr	

Non-active implantable devices

New	BioGlue Surgical Adhesive.	7/31/2018	CryoLife, Inc.	Almarfa Medical	2	A/Ca	
# New	Hoffmann LRF Hexapod Software	8/5/2018	Stryker Europe	Al-Faisaliah Medical System	2	Attac	
New	Quattro Spade Drill	7/31/2018	Cayenne Medical Inc.	ProMedEx	2	A/Ca	

Single-use devices

New	Cellular Matrix BCT-HA, Cellular Matrix A-CP-HA, ArthroVisc40, SkinVisc40	8/2/2018	Regen Lab SA	Bio Standards	FSN	https://nc.mdr	
# New	Pruitt F3 Carotid Shunts with Outlying T-Ports	8/5/2018	LeMaitre Vascular GmbH	Majal Care for Trading Est.	2	Attac	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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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.