



SBED Weekly Update

27-Feb-18

Dear,

SBED team is pleased to inform you that **53** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 2/19/2018 to 2/22/2018
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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Active Implantable Devices

New	Implantable Cardioverter Defibrillators (ICDs)	2/22/2018	Medtronic SA	Medtronic Saudi Arabia	1	https
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Anaesthetic and respiratory devices

New	ELAN 4	2/19/2018	Aesculap	Gulf Medical Co.	2	A/Ca\
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New	ELAN 4 Air System	2/19/2018	Aesculap	Gulf Medical Co.	2	A/Ca\
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#	New	INOflo DS and INOmax DSIR Nitric Oxide Delivery Systems	2/22/2018	Mallinckrodt	Dar Al-Zahrawi Medical Co. LLC	2	
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New	VYLIFE, KIT VYLIFE	2/21/2018	Vygon UK Ltd	el Medical & Trading Co.	FSN	A/Ca\
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Assistive products for persons with disability


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
New	Inex Silicone Devices	2/20/2018	GROUPE SEBBIN SAS	N/A	FSN	A/Ca\	
New	Quick connect scale used with Maxi Sky 2 ceiling lifts	2/20/2018	Arjo Huntleigh	Al-Faisaliah Medical System	FSN	https://nc	
New	Sterilization wrap, JS Series SterilContainer"S2 System	2/19/2018	Aesculap	Gulf Medical Co.	2	https://nc	
#	New	Various Mattress and Seat Cushion System Pumps	2/21/2018	Harvest Healthcare	N/A	2	

Dental devices




New	Dental unit XO	2/20/2018	XO CARE A/S	N/A	FSN	A/Ca\
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Diagnostic and therapeutic radiation devices

#	New	Allura Xper and UNIQ Systems with FlexVision Large Screen Monitor,	2/22/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	
New	Biograph Horizon with VJ20A Software	2/19/2018	SIEMENS	Siemens Medical Solutions	2	https	
New	Fukuda Denshi DynaScope Model DS-8100N/8100M Patient Monitor	2/19/2018	Fukuda Denshi	AL-MIRA CENTRE FOR TRADING COMPANY LIMITED	2	https://nc.mdr	
New	Infinity Acute Care System	2/20/2018	raeger Medical Systems Ir	Draeger Arabia Co. Ltd.	FSN	A/Ca\	
New	MYLAB TWICE EHD	2/20/2018	Esaoite S.p.A.	Salehiya Trading Est.	FSN	A/Ca\	
New	ProGrade Rel.1x	2/20/2018	Philips Medical Systems	s Healthcare Saudi Arabi	FSN	A/Ca\	

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	syngo.via Picture Archiving and Communication Systems Using Software Version VB20A ,	2/22/2018	SIEMENS	Siemens Medical Solutions	2	

Electro mechanical medical devices

	New	Cardio M plus	2/22/2018	Medical Econet GmbH	corals leadership	FSN	A/Cal
	New	Central Venous Catheter.	2/19/2018	Cook Inc,	NAFA Medical	2	A/Cal
	New	Duodenoscope Model ED-530XT ,	2/19/2018	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	FSN	https
#	Update	Ethernet to Fiber-Optic Converters Used with Mako RIO Systems	2/22/2018	Stryker Communications	Al-Faisaliah Medical System	2	
#	New	Model 2008T Hemodialysis Systems with CDX ,	2/22/2018	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	
	New	Pentax Video Duodenoscope..	2/22/2018	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd	2	https
	New	Philips ear thermometer	2/22/2018	Philips Burton	s Healthcare Saudi Arabi	FSN	A/Cal
#	New	Professional 9681 Surgical Clippers	2/19/2018	3M Health Care Ltd	3M company	2	
	New	REANIBEX 300y,REANIBEX 500	2/21/2018	Osatu, S. Coop.	Bassam Trading Company Ltd	FSN	https
	New	ROSA 1.0.2, ROSA 3.0 (Spine application)	2/20/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https
#	New	ROSA Surgical Systems ,	2/22/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	

Hospital hardware

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Enterprise and Citadel Range Beds	2/19/2018	Arjo Huntleigh - electric beds	Gulf Medical Co.	2	https

In vitro diagnostic devices

Update	BORRELIA VIRCLIA IgG MONOTEST	2/20/2018	VIRCELL	ABDULLA FOUAD HOLDING COMPANY	FSN	https
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New	Dimension Vista Calcium Flex reagent cartridge	2/21/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https
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New	Hematoxylin II and Horseradish Peroxidase reagents ,	2/19/2018	Roche Diagnostics GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc
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New	MicroScan LabPro Information Manager System..	2/22/2018	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	FSN	https://nc
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New	Panocell®-10, Ficin Solution	2/19/2018	Immucor GmbH.	Medical supplies & Services Co.Ltd	FSN	https
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New	qLabs PT-INR Monitoring System	2/21/2018	Micropoint Biotechnologies	N/A	FSN	https
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#	New	QUANTA-Lyser 240 Analyzers	2/20/2018	INOVA Diagnostics, Inc.	ABDULLA FOUAD HOLDING COMPANY	2	
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New	revogene	2/21/2018	GenePOC Inc	N/A	FSN	A/Ca
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New	VENTANA anti-ALK	2/21/2018	Roche Diagnostics GmbH	el Medical & Trading Co.	FSN	A/Ca
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Non-active implantable devices

#	New	3M ACE Ankle Braces	2/22/2018	3M Health Care Ltd	3M company	2	
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New	Acetabular Hip Replacement Components	2/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https
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New	AGC Porous Patellar SM and Med	2/19/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https
New	balanSys UNI convex PE inlay x/6, x/7, x/9	2/19/2018	Mathys Ltd Bettlach	Isam Economic Co.	2	https
New	CMI - Collagen Meniscus Implant	2/22/2018	Ivy Sports Medicine	N/A	FSN	https
New	GEOMED CABG PACK PGYBK A & B	2/20/2018	DeRoyal Industries Inc.	Alhaya medical co.	2	https


Reusable devices

New	Hypothermia Caps, Mittens and Slippers	2/19/2018	Southwest Technologies	N/A	2	https
Update	Radiolucent Spine Surgery Frame	2/22/2018	Allen Medical Systems	Reem Alwasat for Trading Company.	2	https

Single-use devices

#	New	1 mL Medallion Syringes ,	2/22/2018	Merit Medical Systems , Inc.	Alhaya medical co.	2	
#	New	16 Fr Open-Tip Standard Silicone 2-Way Foley Catheter Kits	2/22/2018	Mediplus Ltd .	AlShrouk Medical	2	
	New	Ancora 375 Normal	2/21/2018	Eurogine S.L.	N/A	FSN	A/Ca\
#	New	Barrx 360 Express RFA Balloon Catheters ,	2/22/2018	Medtronic SA	Medtronic Saudi Arabia	2	
#	Update	Biatain Ag Cavity Filler	2/22/2018	Coloplast A/S	Hammad Medical Servic	2	
	New	Carefeed Feeding And Drainage Tube	2/20/2018	GBUK Enteral Ltd also trading as Enteral UK	N/A	FSN	https
	New	Uterine Aspiration Tube	2/22/2018	GCMedica Enterprise Ltd	Faalya Advance Compar	FSN	A/Ca\

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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.