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Kingdom of Saudi Arabia
Saudi Food & Drug Authority



المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Medical Devices Sector

Executive Department of Surveillance & Biometrics

قطاع الأجهزة والمنتجات الطبية

الإدارة التنفيذية للرقابة والقياسات الحيوية

SBED Weekly Update

19-Jun-18

Dear,
SBED team is pleased to inform you that **40** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 6/11/2018 to 6/17/2018
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

Hospital Name

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
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Active Implantable Devices

New	Activa PC+S Implantable Neurostimulator (INS)	6/11/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Single Chamber Temporary External Pacemaker 53401	6/17/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	

Anaesthetic and respiratory devices

New	Bivona Tracheostomy Tube Tracheostomy Tubes	6/16/2018	Smiths Medical International Limited	almadar medical Est.	2	https	
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Assistive products for persons with disability

New	ARCUS treatment tables	6/11/2018	Frei AG Aktive Reha	N/A	FSN	A/Ca	
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Diagnostic and therapeutic radiation devices

New	12C (AdaPTinsight)	6/16/2018	IBA Dosimetry GmbH	Al-Faisaliah Medical System	2	A/Ca	
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New	12C, Proteus ONE and Proteus Plus	6/16/2018	IBA Dosimetry GmbH	Al-Faisaliah Medical System	2	A/Ca	
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New	Allura Xper, UNIQ and Centron	6/17/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	A/Ca	
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New	ARCTIC SUN 5000 Temperature Management System	6/17/2018	C R Bard Inc	C.R. BARD Saudi Arabia	FSN	https	
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New	Brilliance 16 P, Brilliance 16 and Brilliance 64	6/16/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	A/Ca	
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# New	CARESCAPE Monitor B650	6/11/2018	GE Healthcare	GE Healthcare	2	ttache	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Carl Zeiss Microscopy for Laser Scanning Microscopes (Cell Observer SD, Laser TIRF and DirectFRAP)	6/16/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	https://nc	
New	Discovery MR750w	6/17/2018	GE Healthcare	GE Healthcare	FSN	A/Ca	
# New	IntelliSpace Portal Systems	6/14/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	ttache	
New	TwinSpeed, Signa Infinity, Excite, Signa Infinity with Excite Technology, Signa Excite 3T, Signa Excite HD 1.5T, Signa Excite HD 3.0T, 1.5T Signa HDx, 3.0T Signa HDx, 1.5T Signa HDxt, 3.0T Signa HDxt, Signa HDi, Signa Vibrant.	6/17/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr.sfda.gov.s	
# New	Various Devices	6/14/2018	GE Healthcare	GE Healthcare	2	ttache	
# New	Various MAC ECG Systems and Wireless Device Servers	6/14/2018	GE Healthcare	GE Healthcare	2	Attac	
# New	Visualase Thermal Therapy Systems.	6/11/2018	Medtronic SA	Medtronic Saudi Arabia	2	ttache	

Electro mechanical medical devices

New	NaturaLyte Liquid Acid Concentrate for Bicarbonate Dialysis, 3.43 Liters	6/16/2018	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	https	
# Update	Prismaflex Control Units ,	6/12/2018	Baxter Healthcare	Baxter AG	2	ttache	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	ROSA Robotized Stereotactic Assistant, Version 2.5	6/16/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc	
New	SIGMA Spectrum Infusion Pump with Master Drug Library (Version 6 and Version 8)	6/16/2018	Baxter Healthcare	Baxter AG	2	https://nc	
New	StraightShot Microdebrider Blades	6/13/2018	Medtronic SA	Medtronic Saudi Arabia	2	A/CaV	

Healthcare facility products and adaptations

New	VOLISTA STANOP, TRIPOD, ACCESS and QUICKLOCK Light heads	6/13/2018	MAQUET Inc	Gulf Medical Co.	2	https	
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In vitro diagnostic devices

New	EZ1 DSP Virus Kit (48)	6/13/2018	QIAGEN Ltd	BDULLA FOUAD HOLDING COMPAN	2	A/CaV	
New	LT-SYS, Based on NAD(H) and/or NADP(H) Reactions	6/11/2018	LABOR + TECHNIK Eberhard Lehmann GmbH	N/A	FSN	https	
New	recomLine ANA/ENA IgG	6/11/2018	Mikrogen GmbH	WAREED ALHAYAT	FSN	A/CaV	
New	remel SUPERPACK CS/ 500 SEG/FLASK, REF R01626, Qty:50, plate label: REMEL MH W/OXACILLIN	6/16/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	2	https://nc	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	The VITEK 2, The PREVI, VIDAS TOXO IgG, Color Gram 2 and Oxidase Reagent	6/16/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https	

New	Troponin T, Liquid Cardiac Control	6/17/2018	Randox Laboratories Ltd.	Bio Standards	FSN	A/CaV	
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Non-active implantable devices

# New	D-Special PROLENE Polypropylene and D-Special PRONOVA Hexafluoropropylene-VDF Sutures	6/11/2018	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	2	Attached	
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New	Prima Plus 4.1 x 11.5mm Implant	6/16/2018	Industries t/a Harry J. Bosworth	Farabi Trading Establishment	2	A/CaV	
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New	Zenith Branch Iliac Endovascular Graft (ZBIS) - Patient Card	6/11/2018	William Cook Europe ApS	NAFA Medical	FSN	https://nc	
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Ophthalmic and optical devices

New	Catalys Precision Laser System..	6/11/2018	Johnson & Johnson Vision Care	Allied Medical International	FSN	A/CaV	
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Reusable devices

# New	FLOSEAL Special Applicator Tips	6/11/2018	Baxter Healthcare	Baxter AG	2	A/CaV	
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# New	Quick Dissect Products	6/11/2018	Surgical Innovations	BDULLA FOUAD HOLDING COMPAN	2	ttache	
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Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Aortic Arterial Cannula 20, 22 and 24 Fr	6/16/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	2	A/Cal	
# New	Carpject Luer-Lock Glass Syringes Containing Naloxone Hydrochloride	6/11/2018	Hospira Inc	AL-KAMAL Import	2	Attac	
# New	Hospira Flexible Intravenous Containers Containing Dextrose and Sodium Chloride	6/11/2018	ICU Medical, Inc	AL-KAMAL Import	2	Attac	
New	Medline SPT Packs	6/11/2018	Medline Industries Inc....	Ikar Establishment	FSN	A/Cal	
Update	Phaseal Secondary Set (C61)	6/17/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	A/Cal	

* 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.