

Ref: WU1823

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 05-Jun-18

Dear,
SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/28/2018 to 6/3/2018
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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Anaesthetic and respiratory devices

#	New	Branded Resuscitator Bags	6/3/2018	Medline Industries Inc....	Ikar Establishment	2	ttache	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Dynarex CGA870 All Brass Oxygen RegulatorAll Brass 025 LPM, Barb & 2DISS Outlet	5/31/2018	Dynarex Corporation	arabianbalsam	2	https://nc	
# Update	ETCO2 OxyMask Oxygen Masks ,	5/28/2018	Southmedic Inc	Healthcare Systems Trading Est.	2	ttache	
New	PARI NaCl Inhalation Solution (NaCl 0,9 %, lot 052C)	5/30/2018	PARI	electronic technicains est	FSN	https	
Dental devices							
New	Respire Pink Hard/Soft	5/31/2018	Respire Medical	N/A	2	A/Cal	
Diagnostic and therapeutic radiation devices							
# New	EMU40/EMU40EX Breakout Boxes	6/3/2018	Natus Medical Inc.	Saudi Health Services Co. Ltd.	2	ttache	
# New	Panasonic Toughbook CF-C2 and CF-SX Laptops	6/3/2018	KONICA MINOLTA, INC	Ahmed Abdulwahed Trading Co	2	Attac	
New	Siemens Biograph Horizon	5/29/2018	Siemens Medical Solutions	Siemens Medical Solutions	2	A/Cal	
# New	Various CT and PET Systems	6/3/2018	GE Healthcare	GE Healthcare	2	ttache	
# New	Vectris SureScan and Vectris Trial Screening Lead Kits	6/3/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac	

Electro mechanical medical devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	HeartStart FRx, HeartStart Home, and Heartstart OnSite AEDs	5/28/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
New	HeartStart MRx Monitor/Defibrillator..	6/3/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	A/Ca	
Update	Sternal Valve Retractors with Atrial and Aortic Attachments	5/31/2018	Genesee BIOMEDICAL, INC.	N/A	2	https	

In vitro diagnostic devices





#	New	Cryptococcal Antigen Lateral Flow Assays.	6/3/2018	Immuno-Mycologics, Inc. (IMMY)	Advanced bio (Al Hyweah Mutaqadim)	2	ttache	
	New	Monoclonal Mouse AntiHuman Cytokeratin, High Molecular Weight, Clone 34βE12	5/30/2018	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	FSN	https://nc	
	New	Oxoid Brilliance MRSA 2 / Brilliance Staph24	5/30/2018	Thermo Fisher Scientific Inc.	ical supplies & Services Co.Ltd Med	FSN	A/Ca	
	New	Syva Emit 2000 Theophylline Assay	5/29/2018	ens Healthcare Diagnostics Pro	AL-KAMAL Import	2	A/Ca	

Non-active implantable devices

	New	Coherex WaveCrest Left Atrial Appendage Occlusion System	5/30/2018	Coherex Medical Inc.	Saudi Import Co. Banaja	FSN	https	
#	New	CopiOs Cancellous Particulate Xenografts	6/3/2018	RTI Surgical, Inc ,	Ebrahim M. Al-Mana & Bros. Co. Ltd	2	ttache	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	CORAIL AMT Neck Trials Surgical Instruments	5/30/2018	DePuy International Limited	Johnson & Johnson Medical Meddile East	FSN	https	
New	QuickFlap, Neuro Implants	5/30/2018	tryker Leibinger GmbH & Co.KG	Zimmo Trading Establishment.	FSN	A/Ca	

Single-use devices

#	New	Alyx Component Collection Systems	5/28/2018	Fresenius Kabi Ltd.	Medical Regulations Gate	2	ttache	
	New	AmerisourceBergen Sterile Latex Surgical Gloves, Powder Free	6/3/2018	WRP ASIA PACIFIC SDN BHD	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https	
#	New	Carpject Luer-Lock Glass Syringes	6/3/2018	Hospira Inc	AL-KAMAL Import	2	ttache	
#	Update	Covidien Endo GIA™ Articulating Loading Units	5/28/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
	Update	Covidien Endo GIA™ Articulating Loading Units	5/30/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
#	New	ReadyFlush Protect Wipes with 3.2% Dimethicone	6/3/2018	Medline Industries Inc....	Ikar Establishment	2	Attac	
	New	Single Use Biopsy Forceps, oval spoonshaped mouth, fenestrated, coated	5/30/2018	MTW-Endoskopie	N/A	FSN	https://nc	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	Various Intravenous Infusion Sets	5/28/2018	Didactic SAS	N/A	2	ttache	



- * 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.