

Ref: WU1824

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

12-Jun-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 6/5/2018 to 6/10/2018
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

Update	Medtronic HeartWare™ HVAD™ System	6/9/2018	HeartWare Inc.	Medtronic Saudi Arabia	FSN	A/Cal	
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Assistive products for persons with disability

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Emergency Room Examination Table	6/6/2018	MAQUET Inc	Gulf Medical Co.	FSN	A/Ca\	

Diagnostic and therapeutic radiation devices

New	ARTIS pheno	6/6/2018	SIEMENS	Siemens Medical Solutions	FSN	A/Ca\	
New	fMRI Hardware System AudioSystem, Version 1.0	6/7/2018	NordicNeuroLab AS	Medical Regulations Gate	2	https	
New	Monaco RTP System. .	6/6/2018	Elekta Inc	Medical Regulations Gate	FSN	A/Ca\	
New	nordicBrainEX	6/5/2018	NordicNeuroLab AS	Medical Regulations Gate	2	A/Ca\	
New	nordicICE v 2.3.14	6/7/2018	NordicNeuroLab AS	Medical Regulations Gate	2	A/Ca\	

Electro mechanical medical devices

New	Bardex Lubricath 3Way 75cc Continuous Irrigation Foley Catheter	6/7/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	https	
New	EXCOR Blood pump	6/9/2018	Berlin Heart AG	N/A	FSN	A/Ca\	
New	Hobbs Bronchial Cytology Brushes	6/5/2018	Hobbs Medical, Inc	Salehiya Trading Est.	2	A/Ca\	
New	M320 Microscope System	6/7/2018	Leica Microsystems Inc.	Al-Faisaliah Medical System	FSN	A/Ca\	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	PENTAX Duodenoscope ED34-i10T	6/9/2018	PENTAX Europe GmbH	ical supplies & Services Co.Ltd Med	FSN	A/Cal	

In vitro diagnostic devices

New	ALAT (GPT) FS (IFCC mod.), ATP Hexokinase FS, CK-MB FS, GLDH FS DGKC (Tests based on NAD(H) and/or NADP(H) reaction)	6/9/2018	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	https://nc	
New	Dimension Integrated Chemistry Systems...	6/7/2018	ens Healthcare Diagnostics Gr	ABDULREHMAN AL GOSAIBI GTB	FSN	A/Cal	
New	Instrument Manager Software.	6/10/2018	Data Innovations	Abbott Diagnostics Division	FSN	A/Cal	
New	Minicon Clinical Sample Concentrators	6/9/2018	Millipore Corporation.	DAR ALAALMIYAH TRADING EST	FSN	A/Cal	
New	N Latex CDT.	6/9/2018	ens Healthcare Diagnostics Pro	AL-KAMAL Import	FSN	A/Cal	
Update	Radiometer ABL800 series with FLEXQ module	6/6/2018	Radiometer America Inc	Salehiya Trading Est.	1	https	
New	RX Imola	6/7/2018	Randox Laboratories Ltd.	Bio Standards	2	A/Cal	
New	STAIA PACK	6/7/2018	Tosoh Bioscience Inc	N/A	2	A/Cal	
New	Tina-quant IgG Gen.2, Urine application	6/9/2018	Roche Diagnostics Corp	OUK, MAAMOUN TAMER & COMP	FSN	A/Cal	
New	Vulcan Fast Red Chromogen Kit	6/10/2018	Biocare Medical LLC	Basic Electronics Company Ltd	FSN	A/Cal	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
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Non-active implantable devices

New	DRILOK THREADED CANNULA	6/5/2018	Stryker Communications	Al-Faisaliah Medical System	2	A/Ca\	
New	HINTEGRA & HINTEGRA SENSITIVE	6/9/2018	tegra LifeSciences ORTHOPAED	Al Ewan Medical Company	FSN	A/Ca\	
New	Legacy Implant Closed-Tray Transfer-Concave Profile 3.5mmD Platform	6/6/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	FSN	https	
New	Replant 5.0mmD Abutment Assy 15 deg Angled	6/6/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	FSN	https	
New	SQUALE	6/9/2018	orthopaedic & Spine Developme	N/A	FSN	A/Ca\	
New	VerteLP Instrument Kit	6/7/2018	VGI Medical, LLC	N/A	2	A/Ca\	

Ophthalmic and optical devices

New	EZ Illuminations Northern Lights EZ Illuminations Galaxy	6/5/2018	SANTA JOY ORNAMENT & GIFTWARE CO	N/A	2	https	
New	NonCertified laser diode component	6/5/2018	li-Vi Incorporated	N/A	2	A/Ca\	

Reusable devices

New	Surgical Instruments and Trials	6/9/2018	anmore Implants Worldwide Lt	Zimmo Trading Establishment.	FSN	A/Ca\	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	WASSENBURG WD440, WD440 PT, WD415 Endoscope WasherDisinfector.	6/6/2018	WASSENBURG Medical B.V	Al Mofadaly Trading Est.	FSN	https	

Single-use devices

New	FARGO Guiding catheter	6/6/2018	Balt Extrusion	Thimar Al Jazirah Healthcare Co.	FSN	A/Cal	
New	Medical Action Industries Inc. Blue OR Towel Non XRay Detectable (6 Towels per Pack)	6/5/2018	Medical Action Industries Inc	Saudi Medical Services SMS	2	https://nc	
New	Multible Catheter, percutaneous, Needls	6/5/2018	Arrow International Inc	Gulf Medical Co.	2	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.