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Kingdom of Saudi Arabia
Saudi Food & Drug Authority



المملكة العربية السعودية
الهيئة العامة للدواء
والدواء

Medical Devices Sector

Executive Department of Surveillance & Biometrics

قطاع الأجهزة والمنتجات الطبية

الإدارة التنفيذية للرقابة والقياسات الحيوية

SBED Weekly Update

27-Jun-18

Dear,

SBED team is pleased to inform you that **24** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 6/18/2018 to 6/19/2018
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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Assistive products for persons with disability

New	Quava	6/19/2018	Vermeiren N.V.	Bio Standards	FSN	A/Cal	
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Diagnostic and therapeutic radiation devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	ECG-Splitter (accessory schwarzer evo)	6/19/2018	Schwarzer Cardiotek GmbH	Bio Standards	FSN	A/Cal	
# New	ErgoJust EEG and ICU Mobile Carts	6/19/2018	Natus Medical Inc	Techno-Orbits Establishment	2	ttache	
# New	IntelliVue Patient Monitors and Avalon Fetal/Maternal Monitors	6/19/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attac	
New	syngo.via VB30A	6/19/2018	SIEMENS	Siemens Medical Solutions	FSN	A/Cal	
# New	Vantage Titan and Vantage Elan MRI Systems	6/19/2018	Canon Europa N.V.	Al Amin Medical Instruments Co. Ltd.	2	Attac	
Electro mechanical medical devices							
# New	Hydroline and Pulse Wave Products	6/19/2018	Cardinal Health..	Medical Technology Establishment	2	ttache	
Healthcare facility products and adaptations							
# New	Pyxis Medication and Supply Management Systems	6/19/2018	CareFusion Alaris A BD Co	Becton Dickinson B.V.	2	Attac	
In vitro diagnostic devices							
Update	ALAT (GPT) FS (IFCC mod.), ATP Hexokinase FS, CK-MB FS, GLDH FS DGKC (Tests based on NAD(H) and/or NADP(H) reaction)	6/18/2018	DiaSys Diagnostic Systems GmbH.	ALGhuyum Scientific Trading	FSN	https://nc	
New	Atellica UAS 800 analyzer..	6/18/2018	healthcare diagnostics product	El Seif Company	FSN	A/Cal	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	AutoDELFI 3.0 rev 5 Software	6/19/2018	inElmer Life and Analytical Scie	ABDULREHMAN AL GOSAIBI GTB	2	ttache	
New	HistoCore Spectra ST	6/18/2018	Leica Microsystems Inc.	Al-Faisaliah Medical System	FSN	A/Ca\	
New	MRSASelect II	6/18/2018	Bio-Rad Laboratories Inc	Al-Jeel Medical & Trading Co. LTD	FSN	A/Ca\	
# New	Oxoid Staph/Strep Selective Agar	6/19/2018	Thermo Fisher Scientific Inc.	ical supplies & Services Co.Ltd Med	2	ttache	
New	Thermo Scientific Oxoid BIGGY Agar 500g CM0589B	6/19/2018	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	FSN	https	

Non-active implantable devices

# New	ADVANSYS MLP/DLP, ADVANSYS TTC, TIBIAXYS, and UNI-CP Plates and TIBIAXYS and Large QWIX Cortical Screws	6/19/2018	Integra LifeSciences	Bio Standards	2	Attac hed	
New	Halo skull pins	6/19/2018	Ossur	Al Ewan Medical Company	FSN	A/Ca\	

Reusable devices

New	Getinge WD15 Claro, Model GE15	6/19/2018	Getinge Disinfection AB	Gulf Medical Co.	FSN	A/Ca\	
New	KeyMed Endosonic Cleaner	6/19/2018	Olympus	Salehiya Trading Est.	FSN	A/Ca\	

Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	ArcRoyal procedure packs containing B.Braun Vasofix Safety ported cannulas	6/18/2018	Owens & Minor	N/A	FSN	https	
#	New Bard 3 Fr Single-Lumen and 4 Fr Dual-Lumen PowerPICC Provena Catheters	6/19/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	Attac	
New	Cirrus-14 Wire Guide AQ Hydrophilic Coating	6/19/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	FSN	https	
New	da Vinci Xi EndoWrist Suction Irrigator.	6/18/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	A/Ca	
#	Update Hospira Flexible Intravenous Containers Containing Dextrose and Sodium Chloride	6/19/2018	ICU Medical, Inc	AL-KAMAL Import	2	Attac	

* 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.