Ref: WUI1541

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 Laboratory equipment and IVD devices Weekly Update | **08-Oct-15**

Dear,
SBED team is pleased to inform you that **7** new FSCA/recalls posted on SFDA website
(Please note: below list of FSCA/ recalls for the period of 9/28/2015 to 10/4/2015
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

In vitro diagnostic devices

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
	New	Alkaline Phosphatase (ALPAMP, ALPDEA and ALPA_c) used on the ADVIA 1200, 1650, 1800, 2400, and XPT Chemistry Systems	9/29/2015	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	2	http://ncmdr.sfda.gov.sa/Secur
	New	chemistry premium plus control	10/4/2015	Randox Laboratories Ltd	Alinfrad Trading Est.	FSN	http://
#	New	Dimension PHOS Reagents	9/28/2015	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	
	New	INSTI HIV-1/HIV-2 antibody test kit	10/4/2015	BioLytical Laboratories	N/A	FSN	http://
#	New	MICroSTREP plus 1 and MICroSTREP plus 2 Panels	9/28/2015	Beckman Coulter, Inc..	ABDULREHMAN AL GOSAIBI GTB	2	
	New	tests based on trinder reactions	10/4/2015	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	FSN	http://

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	VITROS Chemistry Products Calibrator Kit 9	10/4/2015	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	1	http://

* The sign (#) on the left side of the FSN's indicates that the source of this FSN is EC

* 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.