Ref: WU1835

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 29-Aug-18

Dear,
SBED team is pleased to inform you that **22** new FSCA/recalls posted on SFDA website
(Please note: below list of FSCA/ recalls for the period of 8/20/2018 to 8/22/2018
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

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
Anaesthetic and respiratory devices							
New	CPAP Mask Cushion	8/22/2018	Compass Health Brands	N/A	1	A/Ca\	
Diagnostic and therapeutic radiation devices							
Update	AXIOM Aristos MX/VX	8/21/2018	SIEMENS	iemens Medical Solution	FSN	A/Ca\	
New	Blood Pressure Monitor	8/21/2018	Withings Sas	N/A	2	A/Ca\	
New	Hitachi Scenaria CT system	8/21/2018	Hitachi America, Ltd.	N/A	2	https	
New	LiebelFlarsheim Hydra Vision Urology XRay System (DR)	8/22/2018	LIEBEL-FLARSHEIM COMPANY LLC	N/A	2	https://nc	

	Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No	
	New	philips DigitalDiagnost 2.x	8/21/2018	Philips Healthcare	s Healthcare Saudi Arabi	2	A/Ca\		
#	New	Various Endoscopes ,	8/20/2018	Olympus	Salehiya Trading Est.	2			📎
	New	Vertebral Motion Analyzer	8/22/2018	Ortho Kinematics, Inc	N/A	2	A/Ca\		

Electro mechanical medical devices

#	New	Flexible Endoscopes	8/20/2018	Olympus.	N/A	2			📎
#	New	Tissue-Tek AutoSection Microtomes	8/21/2018	Sakura Finetek	Al-Jeel Medical & Trading Co. LTD	2			📎
	New	TriFlo'''' Subglottic Suction System	8/22/2018	Vyaire Medical, Inc..	Bio Standards	1	https		

In vitro diagnostic devices

	New	Salivary Estradiol ELISA	8/21/2018	DRG Instruments GmbH	A FOUAD HOLDING CO	2	A/Ca\		

Laboratory equipment

	New	BD BBL GCLect Agar	8/21/2018	ecton Dickinson & Co. (B	Becton Dickinson B.V.	2	A/Ca\		
	New	bioMrieux VITEK 2 NH ID Test Kit	8/21/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https		

Non-active implantable devices

#	New	Affixus Hip Fracture Nails	8/20/2018	Zimmer Inc.....	Isam Economic Co.	2			📎
	New	CoLink(TM) Lapidus Plate XP	8/22/2018	In2Bones, SAS	N/A	2	https		
	New	Dymaxeon Spine System	8/22/2018	Back 2 Basics Direct LLC	N/A	2	A/Ca\		
	New	ECHO BiMetric and ARCOS Modular Revision Hip System	8/21/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https ://nc		

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Ulnar Osteotomy Compression Plate, Short	8/21/2018	TriMed Ortho	N/A	2	[https]()	

Single-use devices

New	Ext Set	8/21/2018	CU Medical de Mexico, S.A	N/A	2	[A/Ca\\]()	
New	McKesson Powder Free Vinyl Exam Gloves	8/21/2018	Cypress Medical Products.	N/A	2	[https]()	
New	NICO Shepherds Hook Greenberg	8/21/2018	Nico Corp	N/A	2	[https]()	

*** 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.