

Ref: WU1829

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 17-Jul-18

Dear,
SBED team is pleased to inform you that **43** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/9/2018 to 7/15/2018
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

#	New	Master Keys Used with AeroForm Tissue Expanders	7/9/2018	AirXpanders Inc	N/A	FSN	Attac	
	New	Platinum Implantable Cardiac Defibrillator (ICD) and Resynchronisation Therapy Defibrillator (CRT-D)	7/11/2018	LivaNova PLC	cigalah group	2	https://nc	

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Anaesthetic and respiratory devices

New	DORO LUCENT Base Unit, Locking Transitional Member, Transitional Member	7/15/2018	Pro Med Instruments GmbH	Al Amin Medical Instruments Co. Ltd.	FSN	https://nc	
New	PushToSet Intermittent Suction Units	7/12/2018	Ohio Medical Corporation	ABDULREHMAN AL GOSAIBI GTE	2	A/CaV	
New	Suction Catheters, Gastro-enteral Tubes	7/15/2018	ConvaTec	Salehiya Trading Est.	FSN	A/CaV	
Update	Unitque Temp° Pflege Set 1	7/10/2018	GERATHERM MEDICAL AG.	Arfaj Commercial and importing	FSN	A/CaV	

Assistive products for persons with disability

New	FREI AG portable and height adjustable training table	7/12/2018	Frei AG Aktive Reha	N/A	FSN	https	
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Diagnostic and therapeutic radiation devices

New	Leksell GammaPlan 11.1	7/9/2018	Elekta Inc	Medical Regulations Gate	2	A/CaV	
New	Proteus 235, ProteusPLUS	7/15/2018	Ion Beam Applications S.A.	N/A	FSN	A/CaV	

Electro mechanical medical devices

New	10mm 0Deg Infrared Telescope and 10mm 30Deg Infrared Telescope	7/9/2018	Olympus	Salehiya Trading Est.	2	https	
New	BARD MYPICC Kit, REF CK000095B	7/10/2018	Medline Industries, Inc.	ure Development International Lt	2	A/CaV	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Edwards SAPIEN 3 Transcatheter Heart Valve (THV)	7/15/2018	Edwards Lifesciences	Arabian Health Care Supply Co. (AHCSC)	2	https	
New	GETINGE EDS8 (Endoscope Drying and Storage Cabinet) Compressor	7/10/2018	Getinge Disinfection AB	Gulf Medical Co.	2	https	
New	Reliance 1227 Cart and Utensil Washer/Disinfector	7/11/2018	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	2	https	

Healthcare facility products and adaptations

New	P2131 AUTOMATED FIELD STEAM STERILIZER	7/12/2018	Fort Defiance Industries, LLC	N/A	2	https	
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In vitro diagnostic devices

New	AdvanDx QuickFISH Slides	7/15/2018	Opgen Inc	N/A	2	A/Ca	
New	Alinity ci-series System Control Module (SCM) ,	7/12/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https	
New	Alinity s System	7/10/2018	Abbott Laboratories Inc	al supplies & Services Co.Ltd Me	FSN	A/Ca	
New	AmniSure ROM Test	7/15/2018	QIAGEN Inc..	Rokn AI Madaen Est	2	A/Ca	
New	BD FACS Universal Loader	7/12/2018	BD Biosciences	Becton Dickinson B.V.	FSN	A/Ca	
New	CK-MB, opt. DGKC / IFCC; GLDH, DGKC	7/10/2018	DIALAB GmbH	Abdullah A. Baghaffar	FSN	A/Ca	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Dimension Vista® LOCI® Reaction Vessels	7/11/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https	
New	InfectCheck NeoPT	7/10/2018	concile GmbH	N/A	FSN	A/Ca	
New	PDL1 IHC 22C3 pharmDx	7/15/2018	Dako Denmark A/S	Dar Al-Zahrawi Medical Co. LLC	2	A/Ca	

Medical software

New	Guardian Connect Mobile App	7/9/2018	Medtronic SA	Medtronic Saudi Arabia	2	A/Ca	
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Non-active implantable devices

New	AperFix Femoral Implant	7/12/2018	Cayenne Medical Inc.	ProMedEx	2	A/Ca	
New	Apollo XT Suture Anchors	7/15/2018	Valeris Medical, LLC	N/A	2	A/Ca	
New	Müller Straight Stem size 6.25 Lateral	7/10/2018	OHST Medizintechnik AG	N/A	FSN	A/Ca	
New	RT-PLUS MOD FEMORAL COMPONENT RIGHT 4R	7/10/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	https	
New	VISIONAIRE LIGHTWEIGHT ALIGNMENT ROD	7/15/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	https	
New	Zimmer M/L Taper Hip Prosthesis	7/10/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca	


Ophthalmic and optical devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	XION Endoscopy Systems with Windows 10 Pro / LTSB operating systems	7/15/2018	Xion GmbH	ATTIEH MEDICO LTD	FSN	https://nc	

Reusable devices

New	Perifix Catheter Connector.	7/10/2018	B. BRAUN MEDICAL INC...	al supplies & Services Co.Ltd Me	FSN	A/Cal	
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Single-use devices

#	Update	Ancora 375 Normal	7/9/2018	Eurogine S.L.	Regulatory Standards	FSN	ttache		
	New	Coro-Set Bonn Marien-Krankenhaus Custom Kits (5/bx)	7/10/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	FSN	https		
#	New	Craniotomy Kits Containing Symmetry Surgical Electrocautery Forceps, Pencils, and Cords ,	7/9/2018	Medline Industries Inc...	Ikar Establishment	2	Attached		
#	New	Gas In-Line Filters ,	7/9/2018	ect Labor-Technik-Goettingen C	GT Medical	2	ttache		
	New	Hyalomatrix	7/15/2018	Anika Therapeutics Inc.	Pharmaserve Ltd.	2	A/Cal		
	New	MEDRX, Ref 541650R 5Fr X 16" (40cm) Polyurethane Feeding Tube For Pediatric Use	7/15/2018	Canadian Hospital Specialties	N/A	2	https://nc		
	New	Nutriline and Nutriline Twinflo Peripherally inserted central catheters (PICC)	7/9/2018	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	2	https://nc		

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Premicath Neonatal PICC with Stylet .	7/9/2018	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	2	A/CaV	
Update	Safil Sutures ,	7/15/2018	B Braun Surgical SA	Gulf Medical Co.	2	A/CaV	
New	VPS Rhythm ECG , VPS Rhythm ECG , Peripherally Inserted Midline Catheter Kit	7/10/2018	Arrow International Inc	Gulf Medical Co.	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.