

Ref: WU1822

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-May-18

Dear,
SBED team is pleased to inform you that **58** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/21/2018 to 5/27/2018
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	Confirm RX .	5/22/2018	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	A/Cal	
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Update	HeartMate 3 Left Ventricular Assist System.	5/24/2018	Cardiovascular and Neuromod	Arabian Trade House Est.	FSN	A/Cal	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
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Anaesthetic and respiratory devices

#	New	AirLife Resuscitation Devices	5/21/2018	Vyair Medical, Inc..	Bio Standards	2	ttache	
	Update	Da Vinci® Xi EndoWrist Stapler Release Kit	5/23/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	A/Cal	
	New	Fabius, Apollo & Perseus devices	5/22/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	A/Cal	
	New	HexaPOD evo RT System	5/23/2018	Elekta Inc	Medical Regulations Gate	FSN	A/Cal	
	New	INSPIRE 6 and INSPIRE 8 hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir	5/24/2018	LivaNova Deutschland GmbH.	Arabian Trade House Est.	2	https://nc	




#	New	PRO-NOX Nitrous Oxide Delivery Systems	5/22/2018	CAREstream Medical Ltd	N/A	2	ttache	
	New	Teleflex MEDICAL LMA(TM) MADgic	5/24/2018	Teleflex Medical..	Gulf Medical Co.	2	A/Cal	

Dental devices





	New	Tapered Screw-Vent Implants with 0.5 mm Machined Collar, MTX Surface and Microgrooves	5/24/2018	Biomet 3i Inc	Asnan Medical Services	2	https://nc	
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Diagnostic and therapeutic radiation devices

	New	AXIOM Artis and Artis Zee Systems	5/24/2018	SIEMENS	Siemens Medical Solutions	FSN	A/Cal	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Philips Volcano Core M2 Imaging Systems	5/22/2018	VOLCANO CORPORATION	Ikar Establishment	2	A/CaV	
# New	Symbia T and Symbia Intevo Systems Using CARE Dose4D Algorithms.	5/21/2018	SIEMENS	Siemens Medical Solutions	2	Attac	
# New	TX MicroTip Cartridge Systems	5/27/2018	Tenex Health	N/A	2	ttache	
# New	Various Discovery Nuclear Scanning Systems	5/27/2018	GE Healthcare	GE Healthcare	2	Attac	

Electro mechanical medical devices

New	Arcomed Volved Set for Pump Type Volved µVP 5005/7000 PVC and Gravity Use	5/24/2018	Phoenix Srl	Dar Al-Zahrawi Medical Co. LLC	2	https://nc	
# New	BD SmartSite Administration Sets	5/21/2018	Becton, Dickinson And Company	Medical Regulations Gate	2	ttache	
Update	CORE Suction Irrigation Handpieces	5/22/2018	ConMed Corporation.	ProMedEx	2	A/CaV	
# New	Mega Power Electrosurgical Generators	5/27/2018	Megadyne Medical Products Inc	n & Johnson Medical Saudi Arabia L	2	ttache	
# New	Model JF-140F Duodenoscopes	5/27/2018	Olympus	Salehiya Trading Est.	FSN	ttache	
# New	Model PJF-160 Duodenoscopes ,	5/21/2018	Olympus	Salehiya Trading Est.	2	ttache	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	SYMMETRY Olsen Single-Use Electrocautery Forceps, Pencils, and Cords	5/21/2018	Symmetry Surgical	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac	

Healthcare facility products and adaptations

New	Neutral Cleaner Sponges, 3 Enzy Sponges	5/24/2018	MDD Company GmbH	N/A	FSN	A/Cal	
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Hospital hardware

New	P.R.O. Matt and ProCair Mattresses	5/24/2018	Joerns Healthcare Limited	Al-Jeel Medical & Trading Co. LTD	FSN	A/Cal	
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In vitro diagnostic devices






# New	NEOLISA Chromogranin A Reagents ,	5/22/2018	Euro Diagnostica	Saudi Import Co. Banaja	2	ttache	
New	ABL90 FLEX analyzer.	5/24/2018	Radiometer Medical	Salehiya Trading Est.	FSN	A/Cal	
# New	ALBAclone Anti-N Murine Monoclonal IgG Vials	5/22/2018	Quotient Diagnostics Ltd	N/A	2	Attac	
New	Cobas	5/27/2018	Roche Diagnostics Corp	OUK, MAAMOUN TAMER & COMP	2	ttache	
New	iChem(R) VELOCITY Urine Chemistry Strips	5/22/2018	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	A/Cal	
# New	i-STAT 1 Wireless Analyzers and i-STAT Alinity Instruments	5/27/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	2	Attac	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	Liquichek Urine Chemistry Control, Level 2	5/22/2018	Bio Rad.	Al-Jeel Medical & Trading Co. LTD	FSN	A/Ca\	
New	Liquid Assayed Specific Protein Controls	5/24/2018	Randox Laboratories Ltd.	Bio Standards	FSN	A/Ca\	
New	MIA FORA NGS HLA Server and Software versions 3.0 and 3.1.	5/24/2018	BioArray Solutions Ltd	N/A	2	https	
New	R30855101 - Salmonella paratyphi A-H Stained Suspension.	5/24/2018	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	2	https	
New	Thermo Scientific Remel Agglutinating Sera	5/24/2018	Thermo Fisher Scientific Inc.	ical supplies & Services Co.Ltd Med	FSN	A/Ca\	
# New	VERIGENE Enteric Pathogens Nucleic Acid Test Cartridges ,	5/22/2018	Luminex Molecular Diagnostics Inc	Hatem I. Alshedwy Comm. Est.	2	Attac	


Non-active implantable devices

New	5o (degree) GENESIS(R) II VALGUS BUSHING	5/24/2018	Smith & Nephew inc	Smith & Nephew inc	2	A/Ca\	
New	AMENDIA Omega Lumbar Interbody Fusion Device	5/24/2018	Spinal Elements	N/A	2	https	
New	Echo Instrument Case Shell - Outer Case Vault Only and Comprehensive Reverse Shoulder Instrument - Outer Case Vault Only	5/22/2018	Zimmer Inc.....	Isam Economic Co.	FSN	https://ncmdr.s	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	GTS Rasp Size +7 / GTS OHST Rasp Size +7	5/23/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	A/Cal	
# New	LFIT V40 Femoral Heads ..	5/27/2018	Stryker Orthopaedics	Zimmo Trading Establishment.	2	ttache	
New	Milling Drill D1.5mm	5/23/2018	Alpha- Bio Tec. Ltd.	N/A	FSN	A/Cal	
New	Synthes Torque Limiting Handle	5/24/2018	Synthes GmbH.	n & Johnson Medical Saudi Arabia l	2	A/Cal	
New	TC-PLUS Advanced Primary Femoral Trial	5/24/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	A/Cal	
New	Traction cables for our ulrich medical traction cable winch retractors	5/23/2018	Ulrich GmbH & Co. KG	Isam Economic Co.	FSN	https	
# New	Various Trauma Guidewires	5/27/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	ttache	
New	Werber Countersink Cannulated for micro CBS screws	5/23/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https	
Reusable devices							
# New	Aluminum Dewars ,	5/22/2018	Chart Industries Inc	N/A	2	ttache	
Single-use devices							
New	ARROW Multiple-Lumen Central Venous Catheter	5/23/2018	Arrow International Inc	Gulf Medical Co.	FSN	https	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)	
#	New	Fresh Whole Blood Transfusion Sets and Fresh Whole Blood Donor Sets Containing BD Vacutainer EDTA Top Tube	5/21/2018	Combat Medical Systems	N/A	FSN	Attached	
	New	Infusion Stopcock Blister Pack Integrity	5/23/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	FSN	A/Ca	
#	New	Micro Seldinger Kits ,	5/22/2018	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	2	ttache	
#	New	Procedure Kits Containing Galt Introducer Sheaths	5/22/2018	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac	
	New	Procedure packs containing specific introducers (with and without guidewires), peelaway sheaths and peelaway dilators.	5/23/2018	Kimal plc	Gulf Medical Co.	FSN	https://nc	
#	New	Procedure Trays Containing BD PosiFlush Heparin Lock Flush Syringes and Prefilled Normal Saline Syringes	5/22/2018	Merit Medical Systems, Inc..	Medical Technology Establishment	2	Attac hed	
#	New	Shadow Holdings Various Remedy Products	5/22/2018	Medline Industries Inc...	Ikar Establishment	2	ttache	
	New	Southmedic Sterile Disposable Scalpel Rx only	5/22/2018	Southmedic Inc	Healthcare Systems Trading Est.	2	https	
#	New	Vascular Solutions Drainer Centesis Catheters ,	5/21/2018	Vascular Solutions Inc	Medical Technology Establishment	2	Attac	

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- * 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.