



SBED Weekly Update 25-Sep-18

Dear,
SBED team is pleased to inform you that **49** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 9/17/2018 to 9/20/2018
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
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Active Implantable Devices

New	Cardiac Resynchronization Therapy pacemakers (VISIONIST™, IV,) and pacemakers (ACCOLADE™, PROPONENT™ and ESSENTIO™)	9/20/2018	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/C	
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New	LATITUDE™ Programmer ,	9/19/2018	Boston Scientific Cardiac Rhythm	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc	
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Anaesthetic and respiratory devices

New	EO-150 ventilator.	9/17/2018	EOVE	N/A	FSN	A/Ca	
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New	Mayfield tracker	9/17/2018	Scopis GmbH	N/A	FSN	A/Ca	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Tthe pump head s.pump	9/18/2018	Medos Medizintechnik AG.	Al Mofadaly Trading Est.	FSN	A/Ca\	

Dental devices

New	RePlant Precision IO Scan Adapter	9/18/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for	FSN	https://nc	
New	Unity Drill Assembly Unit, .021	9/18/2018	Coltene Whaledent Inc.	Asnan Medical Services	FSN	https://nc	

Diagnostic and therapeutic radiation devices

New	CyberKnife Robotic Radiosurgery System..	9/17/2018	Accuray Inc	Gulf Medical Co.	FSN	https://nc	
New	Mon-a-Therm Foley catheters with temperature sensors	9/17/2018	Degania Silicone, Ltd	N/A	FSN	https://nc mdr.	
New	Samsung Digital X-Ray System ,	9/19/2018	Samsung Electronics	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https://nc	
New	Sysmex Fluorocell PLT	9/20/2018	Sysmex America Inc (N/A)	N/A	2	A/Ca\	
New	Xper Flex Cardio Physiomonitring System.	9/18/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc	

Electro mechanical medical devices

New	AK 98 Hemodialysis Devices ,	9/19/2018	Baxter Healthcare	Baxter AG	2	https://nc	
New	Alaris / Asena CC, GH Syringe Pump	9/17/2018	Becton, Dickinson And Company	Medical Regulations Gate	FSN	https://nc	
New	Neuro Omega	9/19/2018	pha Omega Engineering Lt	N/A	FSN	A/Ca\	
New	Sterile single use electrosurgical pencil/HCP-05	9/17/2018	WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.	Teriag International	FSN	https://nc mdr.	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	VTI 8 MHz Surgical Doppler	9/20/2018	Vascular Technology, Inc.	N/A	2	https://nc	

Hospital hardware

New	Strap Gripper, for Liko MultiRall 200	9/17/2018	Hill Rom Inc	Medical regulations gate	FSN	https://nc	
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In vitro diagnostic devices

New	ADVIA Chemistry Creatine Kinase (CK_L) System Reagent ,	9/19/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://nc.mdr	
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New	Alere Triage NT-proBNP Test	9/17/2018	Alere	Techno-Orbits Establishment	FSN	https://nc	
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New	Alinity i Processing Module ,	9/19/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https://nc	
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Update	ARCHITECT ICT Modules	9/19/2018	Abbott Laboratories Inc	pplies & Services Co.Ltd	FSN	A/CaV	
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New	Automated Hematology Analyser XN-Series	9/18/2018	Sysmex Europe GmbH.	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc	
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New	BOND Slide Labeller Zebra Printer Power Supply Unit (PSU) for use with BOND-III and BOND-MAX instruments.	9/19/2018	Leica Microsystems, Inc.	Salehiya Trading Est.	2	https://nc.mdr.sfda.gov.s	
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New	ClinRep Complete Kit for Antiepileptics in Serum / Plasma with UHPLC	9/18/2018	Recipe Chemicals & Instruments GMBH	NAIZAK GLOBAL ENGINEERING LAB SYSTEMS	FSN	https://nc.mdr	
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New	D-100 Haemoglobin Testing System	9/18/2018	Bio-Rad Laboratories Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc	
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New	Enzymatic Creatinine OSR6x204, HDL Cholesterol OSR6x87, Lipase OSR6x30 and Uric Acid OSR6x98	9/18/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	FSN	https://nc.mdr.sfda.gov.s	
New	FilmArray Blood Culture Identification Panel-BCID	9/17/2018	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc	
New	FLEX Monoclonal Mouse Anti-Human Progesterone Receptor, Clone PgR 1294	9/18/2018	Dako North America Inc	Dar Al-Zahrawi Medical Co. LLC	FSN	https://nc.mdr.sfda	
New	IgG4 Food Screen 280 ELISA	9/17/2018	Tecan Sales Austria GmbH	Samir Photographic Supplies Co. Ltd.	FSN	https://nc	
New	Power adapter for the HemoPoint H2 meter, Model G3000 series	9/17/2018	Stanbio Laboratory, LP	Al Nahir Trading Co	2	https://nc.mdr	
New	SIRscan discs Amoxicillin 2 µg + clavulanic acid 1 µg	9/18/2018	I2A - Intelligence Artificielle Applications SA	N/A	FSN	https://nc.mdr	
New	Taenia solium IgG ELISA	9/17/2018	Tecan Sales Austria GmbH	Photographic Supplies Co	FSN	A/Ca	
New	VIROTROL HIV-1 Ag ,	9/18/2018	Bio Rad.	el Medical & Trading Co.	2	A/CaV	

Non-active implantable devices

New	Cannulated Tap, 5.5 mm	9/18/2018	icotec AG	N/A	FSN	A/Ca	
New	P.F.C. SIGMA Revision Knee System Distal Augment	9/20/2018	DePuy International Limited	Johnson & Johnson Medical Meddile East	2	https://nc.mdr	
New	Powerflex PRO PTA balloon dilation ,	9/19/2018	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	STERILE FLUTED HEADLESS 1/8" PIN 3.5" LONG	9/18/2018	Stryker Orthopaedics	Zimmo Trading Establishment.	FSN	https://nc.mdr	

New	T.E.S.S Glenoid Drill 5mm	9/17/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	A/Cal	
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New	Vitality Shear-off Set Screw	9/17/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https://nc	
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Ophthalmic and optical devices

New	AWC-Additional Working Channel	9/17/2018	Ovesco Endoscopy AG	Arabian Trade House Est.	FSN	https://nc	
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Single-use devices

New	Haemostatic Valves	9/18/2018	Medical Device (Shenzhen)	Narjis Aljazirah Medical	FSN	A/Cal	
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New	HICKMAN® Central Venous Catheter ,	9/19/2018	C R Bard Inc	C.R. BARD Saudi Arabia	FSN	https://nc.mdr	
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New	Intrafix SafeSet Standard, 180 cm	9/17/2018	B Braun Medical Inc	Medical supplies & Services Co.Ltd	FSN	https://nc	
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New	LONE STAR® SINGLE-USE ELASTIC STAYS	9/20/2018	Cooper Surgical, Inc.	Cure Development International Ltd	FSN	https://nc	
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New	Medline 0.9 Sodium Chloride Injection	9/20/2018	Medline Industries Inc...	Ikar Establishment	2	https://nc	
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New	Sterile single use Laryngeal Mask Airway	9/20/2018	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	FSN	https://nc	
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New	Urine Collection BARD Midstream Catch Kit with Funnel Connector	9/17/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2	https://nc.mdr	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Various Brand of Peripheral Venous Catheter.	9/18/2018	Mediplus Ltd .	AlShrouk Medical	FSN	https://nc.mdr.	

* 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.