



SBED Weekly Update 23-Oct-18

Dear,
SBED team is pleased to inform you that **79** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/15/2018 to 10/21/2018
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	Impella Heart Pumps	#####	ABIOMED Inc	Gulf Medical Co.	FSN	A/Ca	
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Anaesthetic and respiratory devices

New	CONTAINERS, Cryogenic tanks	10/16/2018	CRYO DIFFUSION S.A.S.	N/A	FSN	https	
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New	FMI gear kit, GMM Tables starting from serial number 010/313 until serial number 33130	10/16/2018	General Medical Merate SpA..	Bio Standards	FSN	https://nc.mdr.	
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New	SpO2-Controller "SP02C" of the ventilator SOPHIE	10/21/2018	Fritz Stephan GmbH.	Al Khateeb United Trading Est.	FSN	https	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	TEXAS Bronchoscope Tube	10/16/2018	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	https	

Assistive products for persons with disability

New	Parking brake for wheelchairs	10/21/2018	Etac	Medicare Center	FSN	https	
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Dental devices

New	Implant Direct Legacy Implant	10/15/2018	Implant Direct Sybron Manufacturing,LLC	Ahmad Abdullah Alzoman Est. for trading	2	https	
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New	Titanbase MyPlant II	#####	Hager & Meisinger GmbH	el Medical & Trading Co.	FSN	A/Ca	
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Diagnostic and therapeutic radiation devices

New	Artis zee ceiling systems.	#####	SIEMENS	iemens Medical Solution	FSN	A/Ca	
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New	Biograph mCT and Biograph Horizon Systems ,	10/15/2018	SIEMENS	Siemens Medical Solutions	2	https://nc	
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New	Brilliance 6, Brilliance 10, Brilliance 16 & 16 Power, Brilliance 40, Brilliance 64	10/21/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc	
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New	CombiDiagnost,	#####	Philips Medical Systems	s Healthcare Saudi Arabi	FSN	A/Ca	
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#	New	DRX-Ascend and Q-Rad Digital Radiography Systems Using Siemens 3D Lifting Columns ,	10/21/2018	Carestream Health	Samir Photographic Supplies Co. Ltd.	2		
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New	Evo Excel ECG Power Outlet	10/21/2018	SIEMENS	Siemens Medical Solutions	FSN	https	
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New	LOGIQ E10 ultrasound systems (when used with TEE probes)	10/15/2018	GE Healthcare	GE Healthcare	2	https://nc	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	NANOKNIFE DISPOSABLE SINGLE ELECTRODE PROBES	10/21/2018	AngioDynamics, Inc.	Medical Regulations Gate	FSN	https://nc	
New	RayStation and RayPlan , 4.5, 4.7, 5, 6, 7	10/15/2018	RaySearch Laboratories AB	Creative Healthcare Establishment	2	https	
New	UV THERAPY SYSTEM UV 7001	10/21/2018	Herbert Waldmann GmbH & Co. KG	Al-Jeel Medical & Trading Co. LTD	FSN	https	

Electro mechanical medical devices

#	New	Arrow AutoFuser Disposable Pain Control Pumps	10/18/2018	Arrow International Inc	Gulf Medical Co.	FSN		
	New	BioFlo Port with ENDEXO and PASV Technology	10/15/2018	AngioDynamics Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	https	
	New	CareLink 2090 and CareLink Encore 29901/29901A Programmers	10/17/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc.mdr	
#	New	Cera Vascular Plug Systems	10/16/2018	Lifetech Scientific (Shenzhen) Co., Ltd.	Ameesa Medical Instruments	FSN		
	New	CUSA Excel (Excel+) Ultrasonic Surgical Aspirator System ,	10/15/2018	Integra LifeSciences	Bio Standards	2	https://nc	
	New	DIAMONDBACK 360 Peripheral Orbital Atherectomy System..	10/17/2018	Cardiovascular Systems, Inc	N/A	2	https://nc	
	New	IVUS Catheter, Visions PV .035 Intravascular Ultrasound Catheters	10/21/2018	VOLCANO CORPORATION	Ikar Establishment	FSN	https://nc	
	New	Reprocessed Agilis Steerable Introducer	10/15/2018	Johnson & Johnson Medical GmbH	Johnson & Johnson Medical Saudi Arabia	2	https	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Thoratec CentriMag Motor, Model: 102956	10/17/2018	Thoratec Corp	Arabian Trade House Est.	2	https	

New	WIDEX BABY440	#####	Widex A/S	Abdul Latif Basha Medical	2	A/Ca	
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Hospital hardware

# New	Nära Hospital Bassinets	#####	Stryker	el Medical & Trading Co.	2		
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In vitro diagnostic devices

New	Access 2 Immunoassay System...	10/17/2018	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	https	
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Update	ADVIA Centaur CKMB Calibrator Bias and Out of Range Results Using Master Curve Material (MCM)	10/21/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr.sfda.	
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# New	ALBAclone Anti-Leb Reagents	10/18/2018	Quotient Diagnostics Ltd	N/A	FSN		
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New	Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module ,	10/15/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc	
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New	Alinity i Free T3 Reagent Kit ,	10/15/2018	Abbott	Medical supplies & Services Co.Ltd	FSN	https	
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New	ARCHITECT Free T3 Reagent Kit, ARCHITECT Total T3 Reagent Kit v ,	10/15/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc	
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New	BD MAX System ,	#####	BD Biosciences	Becton Dickinson B.V.	FSN	A/Ca	
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# New	CoaguChek XS Test Strips INST 48CT	10/18/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN		
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	ColoVantage Home-Faecal Immunochemical Test Kits.	10/17/2018	Enterix Pty Ltd	N/A	2	https://nc	
New	Contour Next Blood Glucose Test Strips, CONTOUR XT Blood Glucose Meter	10/16/2018	ASCENSIA DIABETES CARE HOLDINGS AG	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN	https://nc.mdr.	
New	Dimension Integrated Chemistry Systems ,	10/15/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https	
New	Evidence Analyser Operator Manual	10/18/2018	Randox Laboratories Ltd.	Bio Standards	FSN	https	
New	Free and Total Protein S ELISA Kit	10/17/2018	Helena Biosciences Europe	Fuad Abdul Jalil Al Fadhli & Sons	2	https	
New	HemosIL ReadiPlasTin.	#####	Instrumentation Laboratory	A FOUAD HOLDING CO	2	A/Ca	
New	HEPATITIS E VIRCLIA IgM MONOTEST	10/16/2018	VIRCELL	ABDULLA FOUAD HOLDING COMPANY	FSN	https	
New	RAPIDPoint 500 Blood Gas Systems.	10/15/2018	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros.	2	https	
# New	Roche Various Chemstrip Test Strips Used with Urisys 1100 Urine Analyzers	10/18/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN		
New	RX Monaco ,	#####	Randox Laboratories Ltd.	Bio Standards	FSN	A/Ca	
New	VITROS® Chemistry Products dLDL Reagent ,	10/18/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	https	

Medical software

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	SPECTRUM IQ INFUSION SYSTEM WITH DOSE IQ SAFETY SOFTWARE	10/17/2018	Baxter Healthcare	Baxter AG	2	https://nc	

Non-active implantable devices

# Update	Affixus Hip Fracture Nails.	#####	Zimmer, INC....	Medical Regulations Gate	2		
New	Avantage Acetabular Shell Inserter Instrument for hip	10/16/2018	Zimmer, INC....	Medical Regulations Gate	FSN	https://nc	
New	AVS Aria Cage	#####	Stryker Spine SA	Medical Express Services	2	A/Cal	
New	Curion Curisoft	#####	Medeco BV	N/A	FSN	A/Cal	
New	Drill, AO Coupling, Ø 3 mm for 13 mm screw	10/21/2018	icotec AG	N/A	FSN	https	
New	H3 Poly Inlay	#####	DT MedTech	N/A	FSN	A/Cal	
New	INSORB SUBCUTICULAR SKIN STAPLER.	10/15/2018	Incisive Surgical Inc	Arouja Trading Establishment	2	https	
New	Inter-atrial Shunt Device (IASD) System II	10/21/2018	Corvia Medical, Inc.	N/A	FSN	https	
# New	RapidFlap System SpinDown Clamps	10/16/2018	Zimmer, INC....	Medical Regulations Gate	FSN		
New	Revision femoral head #L, #XL	10/21/2018	Limacorporate S.p.a.	N/A	FSN	https	
New	ROMEO 2 PAD PAD-IM WT XX-S	10/16/2018	SPINEART	Tina Medix Technologies Int. Co.	FSN	https	
New	SILK+ / VASCO+	#####	Balt Extrusion	nar Al Jazirah Healthcare	FSN	A/Cal	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	StageOne Select, Hip Cement Spacer Molds	10/16/2018	Zimmer, INC....	Medical Regulations Gate	FSN	https	
Update	StrataMR Adjustable Valves & Shunts .	10/21/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	https	
New	Tibial Alignment Guide.	#####	Exactech	N/A	2	A/Ca	
New	TITAN 3-D Wedge, Evans, Large, 10mm	10/21/2018	Paragon 28, Inc	N/A	2	https	
Update	VERASENSE ZBH-PSNCREF311-R CR E-F/3-11 Right.	10/15/2018	Orthosensor Inc.	Smith & Nephew inc	2	https://nc	
New	YUKON OCT Spinal System Polyaxial Screw Size 3.5 x 34mm	10/15/2018	K2M Inc.	Bio Standards	2	https://nc	

Ophthalmic and optical devices

New	Carl Zeiss Meditec AG IOLMaster 700	10/21/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	2	https	
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Reusable devices

New	Valeris Medical Apollo Medial Suture Anchor	10/17/2018	Valeris Medical, LLC	N/A	2	https	
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Single-use devices

New	Ambu Aura40 Standard	#####	MED HEALTH BUSINESS C	ed Specialty Projects Trac	2	A/Ca	
New	Boot Compression Wrap	#####	Medline Industries, Inc.	Development Internation	2	A/Ca	
New	Buddy Disposable Sets	#####	Belmont Instrument Corp	oken Al Mothmir Trading	2	A/Ca	
New	Level 1 Foley Catheters with Temperature Sensors	10/21/2018	Smiths Medical International Limited	almadar medical Est.	FSN	https	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Lifeshield Primary Plum Set 15 Micron Filter in Sight Chamber, CLAVE Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Tubing, Secure Lock 272 cm / 23 mL	10/21/2018	ICU Medical, Inc	AL-KAMAL Import	2	https://ncmdr.sfda.gov.sa/Secure/	
New	Mon-a-ThermT Foley catheters with temperature sensors	10/16/2018	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	https://nc	
# New	Parietex Composite Parastomal Mesh	10/18/2018	Medtronic SA	Medtronic Saudi Arabia	FSN		
New	Portex Bivona Inner Cannula for Bivona Adult Tracheostomy Tubes	10/16/2018	Smiths Medical International Limited	almadar medical Est.	FSN	https://nc	
New	Pruitt F3-S Polyurethane Outlying Carotid Shunt ,	10/17/2018	LeMaitre Vascular GmbH	Majal Care for Trading Est.	2	https	
New	Reinforced Dual Lumen Cannula, VV13F	10/17/2018	OriGen Biomedical	Arabian Trade House Est.	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.