



SBED Weekly Update

01-May-18

Dear,

SBED team is pleased to inform you that **53** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 4/23/2018 to 4/29/2018
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

Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
-----------	---------------	-----------	--------------	-------------	-------	------

Anaesthetic and respiratory devices

New	Geratherm UniqueResc+	4/24/2018	Geratherm Medical AG	Commercial and importi	FSN	A/Ca\
New	Oxygen Mask for Adults and Children, high concentration	4/29/2018	Asid Bonz GmbH	N/A	FSN	https://nc.mdr
Update	Servo-air, Servo-I, Servo-s, Servo-n and Servo-u	4/26/2018	MAQUET Inc	Gulf Medical Co.	2	https://nc

Dental devices

New	Genesis Surgical Cassette Tapered	4/25/2018	Keystone Dental Inc.	N/A	2	https://nc
-----	-----------------------------------	-----------	----------------------	-----	---	-------------------------------------

Diagnostic and therapeutic radiation devices

New	GMR40	4/25/2018	NeuroLogica	N/A	2	A/Ca\
-----	-------	-----------	-------------	-----	---	-----------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	MEVATRON , ONCOR , PRIMUS	4/25/2018	Siemens Medical Solutions	Siemens Medical Solutions	2	https://nc.mdr
New	RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7)	4/24/2018	RaySearch Laboratories AB	N/A	FSN	https://nc.mdr

Electro mechanical medical devices

New	Advance 35LP LowProfile PTA Balloon Dilatation Catheter	4/29/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	2	https://nc.mdr
New	APOLLOblue (24V)	4/24/2018	P GmbH Laser Applikation	Medical regulations gate	2	A/Ca
New	Cardiovit AT-102 plus.	4/29/2018	Schiller AG	pplies & Services Co.Ltd	FSN	A/Ca
Update	PadPro MiniInfant Multifunction Electrodes 2602 Series	4/24/2018	ConMed Corporation.	ProMedEx	2	https://nc.mdr
# New	Spectra Optia Apheresis Systems	4/29/2018	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	Attached
New	Terumo Advanced Perfusion System 1 Flow Module.	4/23/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	https://nc.mdr

In vitro diagnostic devices

New	Alere Afinion ACR Control	4/29/2018	Alere.	Waleed Al-Madani Est.	FSN	A/Ca
New	Combur-Test UX, Chemstrip 10 A, Urisys 1100	4/29/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Dimension® clinical chemistry system and Dimension Vista® System Gentamicin (GENT) Flex® reagent cartridge	4/26/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr.sfd.gov.a/Se
New	Enzymatic assay for the determination of Acetaminophen	4/29/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	https://nc.mdr
New	Hematology Analyzer MEK-9100 Celltac G	4/24/2018	Nihon Kohden Corp.	ABDULLA FOUAD HOLDING COMPANY	FSN	https://nc
New	MATCH IT! DNA software	4/29/2018	Immucor GmbH.	Medical supplies & Services Co.Ltd	FSN	https://nc
New	Oncomine Dx Target Test.	4/23/2018	Life Technologies Limited.	Integrated Gulfbiosystems	2	A/Ca
New	Oxoid Columbia CNA Aesculin Selective Agar / MacConkey Agar No. 3 (mod.)	4/24/2018	Oxoid Ltd Div Thermo Fisher Scientific Inc	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc.mdr.sfd
New	Oxoid CT1412B CPO30 Cefpirome	4/24/2018	Oxoid Ltd Div Thermo Fisher Scientific Inc	Medical supplies & Services Co.Ltd	FSN	https://nc
New	Progesterone Saliva Luminescence Immunoassay	4/24/2018	Tecan Sales Austria GmbH	Samir Photographic Supplies Co. Ltd.	FSN	https://nc.mdr
New	Vitamin D kit, 25-hydroxyvitamin D3	4/24/2018	Tecan Sales Austria GmbH	Samir Photographic Supplies Co. Ltd.	FSN	https://nc
New	Vitamin D total II, Elecsys Vitamin D total II	4/29/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc

Laboratory equipment

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	Acrodose PLus and PL Systems with CLX HP Bags	4/23/2018	Haemonetics Corp.	Arabian Trade House Est.	1	Attac hed

Medical software

# New	iSite and IntelliSpace Picture Archiving and Communications Systems	4/29/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	Attac hed
-------	---	-----------	--------------------	--------------------------------------	---	---------------------------

Non-active implantable devices

New	Blue Suture Grasper	4/24/2018	Ranfac Corp.	Malath Health Medical	FSN	A/Ca\
-----	---------------------	-----------	--------------	-----------------------	-----	-----------------------

New	da Vinci Xi EndoWrist Stapler 45 Reload	4/29/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	https://nc
-----	---	-----------	------------------------	------------------	-----	-------------------------------------

New	Double Blade Shoe F/Unigraft Knife 1.5 Thick X 9MM SKU 6500009	4/23/2018	Ace Surgical Supply Co., Inc	Abdulrehman Algozaibi GTC	2	https://nc.mdr.
-----	--	-----------	------------------------------	---------------------------	---	--

New	Intramedullary Fixation	4/23/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	A/Ca\
-----	-------------------------	-----------	---------------------	-------------------	---	-----------------------

# New	LactoSorb RapidFlap Spindown Instruments	4/23/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	Attac hed
-------	--	-----------	---------------------	-------------------	---	---------------------------

New	LEGION CR HIGH FLEX XLPE	4/29/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	https://nc
-----	--------------------------	-----------	--------------------	--------------------	-----	-------------------------------------

# New	Orthopedic Salvage System Modular Arthrodesis Nail 0° Collar Assemblies with Locking Bolts	4/23/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	Attac hed
-------	--	-----------	---------------------	-------------------	---	---------------------------

New	RegJoint™	4/29/2018	Scaffdex Oy	nce Nfood Medical Com	FSN	A/Ca\
-----	-----------	-----------	-------------	-----------------------	-----	-----------------------

Update	Stage-1 Tissue Punch, Disposable, 4.5mm	4/23/2018	Keystone Dental Inc.	N/A	FSN	https://nc
--------	---	-----------	----------------------	-----	-----	-------------------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	T2 Ankle Arthrodesis / Femur / Tibia / Recon / Greater Trochanter Nails	4/29/2018	Stryker Trauma AG	Al-Faisaliah Medical System	FSN	https://nc.mdr
New	TITAN	4/23/2018	Integra LifeSciences	Bio Standards	2	A/Ca
New	TMJ Concepts PatientFitted TMJ Reconstruction Prosthesis System	4/23/2018	TMJ Solutions Inc	N/A	2	https://nc.mdr.sfda





Ophthalmic and optical devices

New	CTC laser sights	4/25/2018	Crimson Trace Corporation	N/A	2	A/Ca
New	SYNTHESIS ,	4/29/2018	CUTTING EDGE SAS	N/A	FSN	A/Ca


Reusable devices

New	Cook Vacuum Pump	4/23/2018	Cook Medical Europe Limited	Majal Care for Trading Est	2	A/Ca
New	Stryker Toga	4/25/2018	Stryker Instruments	Al-Faisaliah Medical System	2	A/Ca

Single-use devices

#	New	Barrel Clamp Guides Used to Repair Medfusion Syringe Pumps	4/29/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	Attac hed	
#	New	Female to Male Luer Lock Connecting Tubes	4/23/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	2	Attac hed	
#	New	FlowGate 2 Balloon Guide Catheters	4/29/2018	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac hed	
#	New	Multiple Fluid Management Products	4/29/2018	Cardinal-Health	MEDICARE DRUG STORE COMPANY	2	Attac hed	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
New	Portex® Thoracic Catheter and Connecting Tube	4/24/2018	Smiths Medical International Limited	almadar medical Est.	FSN	https://ncmdr	
#	New	PosiFlush Heparin Lock Flush Syringes and Pre-filled Normal Saline Syringes	4/29/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	Attac hed
New	SeQuent Please OTW	4/24/2018	B. Braun Melsungen	ProMedEx	FSN	A/Ca\	
New	Soft-Trans Embryo Transfer Catheter	4/24/2018	Cook Medical Europe Limited	Majal Care for Trading Est.	FSN	https://nc	
New	Sterile Single Use Spinal needle with Introducer ,	4/26/2018	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	FSN	https://ncmdr	
#	New	Transanal Endoscopic Microsurgery (TEM) Tube Sets	4/23/2018	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	2	Attac hed

- * 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.