



SBED Weekly Update 06-Nov-18

Dear,
SBED team is pleased to inform you that **48** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/29/2018 to 11/1/2018
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
------	---------------	-----------	--------------	------------	-------	------	-----------------

Active Implantable Devices

Update	8-Channel Lead for the St. Jude Medical Infinity™ DBS (Deep Brain Stimulation) System	11/1/2018	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr.sfda.gov.sa	
--------	---	-----------	----------------------	-----------------------------------	-----	---	--

# Update	HeartMate 3 Left Ventricular Assist System.	10/29/2018	Abbott Cardiovascular and Neuromodulation	Arabian Trade House Est.	FSN		
----------	---	------------	---	--------------------------	-----	--	--

New	Jarvik 2000 Heart, JHI-212 Y Cable, JHI-202 Lithium-ion Battery Cable, JHI-201 Pedestal Cable, JHI-204 Extension Cable	10/29/2018	Jarvik Heart Inc.	International Medical Supplies Company	FSN	https://nc.mdr.sfda.gov.sa/Se	
-----	--	------------	-------------------	--	-----	---	--

Anaesthetic and respiratory devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	QUADROX-i Neonatal Microporous Membrane Oxygenator	10/31/2018	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	https://nc.mdr	
Update	Fabius with Auxiliary Common Gas Outlet (ACGO)	10/30/2018	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	FSN	https://nc.mdr	
New	TERMINAL UNIT BM O2 NF	10/29/2018	Air Liquide Medical Systems	N/A	FSN	https://nc	

Assistive products for persons with disability

# New	Axor TC Transtibial Protheses	11/1/2018	Integrum	N/A	FSN		
New	compass 530 butterfly/butterfly reverse device	10/31/2018	Proxomed Medizintechnik GmbH	N/A	FSN	https://nc.mdr	
New	Mobilisations-Reharollstuhl Thekla	11/1/2018	Hanse-Medizintechnik Dipl. Ing. P. Hettmer	N/A	FSN	https://nc	

Dental devices

New	Surgical Handpiece	#####	Nakanishi	MAAMOUN TAMER & C	2	A/Cal	
-----	--------------------	-------	-----------	-------------------	---	---------------------------	--

Diagnostic and therapeutic radiation devices

New	Artis zee biplane and Artis Q biplane	10/29/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc	
New	ARTIS zee Systems	10/30/2018	SIEMENS	Siemens Medical Solutions	FSN	https://nc	
# Update	Discovery MR750w	11/1/2018	GE Healthcare	GE Healthcare	FSN		
New	Nuclear Magnetic Resonance Imaging	10/31/2018	GE Healthcare	GE Healthcare	2	https://nc	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	SoKINOX / SERVINO .	#####	Getinge Disinfection AB	Gulf Medical Co.	FSN	A/Cal	

Electro mechanical medical devices

New	Accu-Chek Insight insulin pump system	10/31/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc	
-----	---------------------------------------	------------	------------------------	---------------------------------	-----	-------------------------------------	--

New	EndoWrist® Monopolar Curved Scissors ,	10/30/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	https://nc	
-----	--	------------	------------------------	------------------	-----	-------------------------------------	--

# New	PureFlow-B Solution ,	#####	NxStage Medical, Inc.	DWAN MEDICAL SERVIC	2		
-------	-----------------------	-------	-----------------------	---------------------	---	--	--

New	VirtuoSaph Plus Endoscopic Vessel Harvesting System	10/30/2018	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	2	https://nc mdr.	
-----	---	------------	---	----------------------------	---	---	--

Healthcare facility products and adaptations

New	Heater-cooler (1T), Heater-cooler 3T, FlexTherm	10/31/2018	LivaNova PLC	cigalah group	FSN	https://nc mdr.	
-----	---	------------	--------------	---------------	-----	---	--

In vitro diagnostic devices

New	ABX Pentra Lipase CP	#####	Horiba ABX SAS	brahim Batterjee & Bros.	FSN	A/Cal	
-----	----------------------	-------	----------------	--------------------------	-----	-----------------------	--

# New	ALBAcyte RhD Negative CAT Reagent Red Cells for Antibody Screenings	10/29/2018	Quotient	N/A	2		
-------	---	------------	----------	-----	---	--	--

New	Atellica Sample Handler Prime (SH Prime)	10/31/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc	
-----	--	------------	-------------------------------------	----------------------------	-----	-------------------------------------	--

New	Dimension Vista Intelligent Lab Systems ,	10/31/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	https://nc	
-----	---	------------	-------------------------------------	----------------------------	---	-------------------------------------	--

New	Elecsys FT4 III	#####	Roche Diagnostics Corp	MAAMOUN TAMER & C	FSN	A/Cal	
-----	-----------------	-------	------------------------	-------------------	-----	-----------------------	--

New	iChem VELOCITY Chemistry Strips..	10/31/2018	IRIS Diagnostics	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc	
-----	-----------------------------------	------------	------------------	-----------------------------------	-----	-------------------------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	LeadCare II Blood Lead Test Kit	10/31/2018	Magellan Diagnostics Inc	N/A	2	https://nc	
New	NucliSENS Magnetic Extraction Reagents	10/31/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc	
New	Owren's PT	#####	MediRox	N/A	FSN	A/Ca	
New	RHD BeadChip Kit .	#####	BioArray Solutions Ltd.	pplies & Services Co.Ltd	2	A/CaV	
New	VeriSeq NIPT Solution	#####	Illumina Inc	Bio Standards	FSN	A/Ca	
New	VITEK 2 AST-ST01, ST02, ST03	10/31/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc	
New	XL t(3;3) GATA2/MECOM DF	10/31/2018	MetaSystems	ATTIEH MEDICO LTD	FSN	https://nc	
New	Yersinia enterocolitica IgA ELISA	10/31/2018	IBL International GmbH..	N/A	FSN	https://nc	

Non-active implantable devices

# Update	CyPass Micro-Stents	#####	Alcon Laboratories Inc.	n Medical Instruments Co	FSN		
New	DePuy Synthes 3.0mm Headless Compression Screws	10/31/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	2	https://nc.mdr	
Update	ePTFE Small Beading Vascular Graft Products	10/31/2018	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	https://nc	
# New	Mallory Head Finned Acetabular Shells	10/29/2018	Zimmer, INC....	Medical Regulations Gate	2		
New	MPFL System Implant Set	#####	Xiros Ltd.	N/A	FSN	A/Ca	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Nellix EndoVascular Aneurysm Sealing System..	10/31/2018	Endologix international holding B.V.	Tart Medical	FSN	https://nc.mdr	

Ophthalmic and optical devices

#	New	Raindrop Near Vision Inlays	10/29/2018	Optics Medical	N/A	2			
---	-----	-----------------------------	------------	----------------	-----	---	--	--	--

Reusable devices

New	CHS Custom Convenience Kit	10/31/2018	Custom Healthcare System	N/A	2	https://nc	
-----	----------------------------	------------	--------------------------	-----	---	-------------------------------------	--

New	Tritanium TL Steerable Inserter	10/31/2018	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	2	https://nc	
-----	---------------------------------	------------	---------------------------	------------------------------	---	-------------------------------------	--

Single-use devices

#	Update	ALARIS PCEA ASV Yellow Microbore, ALARIS PCEA ASV Yellow Microbore, ALARIS PCEA Kit ASV Yellow Microbore	11/1/2018	Becton, Dickinson And Company	Medical Regulations Gate	FSN			
---	--------	--	-----------	-------------------------------	--------------------------	-----	--	--	--

New	ARROWgard Blue Plus MultiLumen CVC Kit	10/31/2018	Arrow International Inc	Gulf Medical Co.	2	https://nc	
-----	--	------------	-------------------------	------------------	---	-------------------------------------	--

New	Biopsy Forcept (Alligator with Spike)	10/31/2018	Micro-Tech (Nanjing) Co., Ltd	Tayeb Medical Est	2	https://nc	
-----	---------------------------------------	------------	-------------------------------	-------------------	---	-------------------------------------	--

New	IV administration sets	#####	ICU Medical, Inc	AL-KAMAL Import	FSN	A/Ca	
-----	------------------------	-------	------------------	-----------------	-----	-------------------------	--

New	Sterile Procedure Trays including Kocher clamps	10/31/2018	Medline Industries, Inc.	Cure Development International Ltd	FSN	https://nc	
-----	---	------------	--------------------------	------------------------------------	-----	-------------------------------------	--

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
------	---------------	-----------	--------------	------------	-------	------	--------------------

* 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.