



SBED Weekly Update 20-Mar-18

Dear,
SBED team is pleased to inform you that **29** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 3/12/2018 to 3/15/2018
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
-----------	---------------	-----------	--------------	-------------	-------	------

Active Implantable Devices

Update	Heparin-Coated Guidewires and Catheter Sets	3/12/2018	Cook Medical	NAFA Medical	2	https://nc.mdr
--------	---	-----------	--------------	--------------	---	---

Anaesthetic and respiratory devices

New	APPARATUS, SUCTION, WARD USE, PORTABLE, ACPOWERED	3/14/2018	Laerdal Medical As	Beta Scientific Instruments Co. Ltd	2	https://nc.mdr
-----	---	-----------	--------------------	-------------------------------------	---	---

New	Paragon Oxygenator	3/12/2018	Chalice Medical Ltd	Arabian Trade House Est.	FSN	A/Ca\
-----	--------------------	-----------	---------------------	--------------------------	-----	-----------------------

Update	PMH7000 series Heated humidifiers	3/14/2018	Pacific Medico Co., Ltd	N/A	FSN	https://nc
--------	-----------------------------------	-----------	-------------------------	-----	-----	-------------------------------------

New	Servo-air, Servo-I, Servo-s, Servo-n and Servo-u	3/13/2018	MAQUET Inc	Gulf Medical Co.	2	https://nc
-----	--	-----------	------------	------------------	---	-------------------------------------

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

Dental devices

New	Stage-1 Tissue Punch, Disposable, 4.5mm	3/12/2018	Keystone Dental Inc.	N/A	FSN	https://nc
-----	---	-----------	----------------------	-----	-----	-------------------------------------

Diagnostic and therapeutic radiation devices

New	HPR45i	3/14/2018	Fcare systems NV	Banader gulf company	FSN	A/Ca
-----	--------	-----------	------------------	----------------------	-----	-------------------------

New	Proteus 235..	3/12/2018	on Beam Applications S.A	N/A	2	A/Ca
-----	---------------	-----------	--------------------------	-----	---	-------------------------

New	ProteusONE	3/12/2018	on Beam Applications S.A	N/A	2	A/Ca
-----	------------	-----------	--------------------------	-----	---	-------------------------

Electro mechanical medical devices

New	da Vinci X Patient Side Cart Arm Controller Joint Circuit Boards	3/15/2018	Intuitive Surgical Inc	Gulf Medical Co.	2	https://nc.mdr
-----	--	-----------	------------------------	------------------	---	---

Hospital hardware

New	IMRIS ORT100 and ORT300 Operating Room Tables	3/12/2018	Deerfield Imaging	Gulf Medical Co.	2	https://nc.mdr
-----	---	-----------	-------------------	------------------	---	---

In vitro diagnostic devices

Update	AQUIOS CL Flow Cytometry System.	3/12/2018	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	2	https://nc
--------	----------------------------------	-----------	-----------------	-----------------------------------	---	-------------------------------------

New	Atellica Solution	3/12/2018	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/Ca
-----	-------------------	-----------	---------------------------	---------------------	-----	-------------------------

New	cobas 6000, cobas 8000	3/15/2018	Roche Diagnostics Corp	MAAMOUN TAMER & C	2	A/Ca
-----	------------------------	-----------	------------------------	-------------------	---	-------------------------

New	IBDoc, component: CalApp Reader (software)	3/14/2018	BUHLMANN LABORATORIES AG	MEDICAL INNOVATIONS EST.	FSN	https://nc
-----	--	-----------	--------------------------	--------------------------	-----	-------------------------------------

New	iSTAT DE	3/12/2018	Abbott Point of Care	ppplies & Services Co.Ltd	2	A/Ca
-----	----------	-----------	----------------------	---------------------------	---	-------------------------

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Thermo Scientific Oxoid Brilliance Salmonella Agar Base	3/14/2018	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	FSN	https://nc.mdr

New	VIDAS LH	3/14/2018	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca
-----	----------	-----------	----------------	--------------------------	-----	-------------------------

Laboratory equipment

New	Difco Agar Noble, 500g bottle	3/12/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	https://nc
-----	-------------------------------	-----------	-----------------------------	-----------------------	---	-------------------------------------

New	Via2BagDirect Connect	3/14/2018	dimop Medical Projects L	N/A	2	A/Ca
-----	-----------------------	-----------	--------------------------	-----	---	-------------------------

Non-active implantable devices

New	Alignment guide 55° of TOP II Impactor Handle	3/12/2018	Waldemar LINK GmbH & Co	Abdul Jaleel Ibrahim Batterjee Sons	FSN	https://nc
-----	---	-----------	-------------------------	-------------------------------------	-----	-------------------------------------

New	Avenir Muller Stem (Hip implant)	3/12/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https://nc
-----	----------------------------------	-----------	---------------------	-------------------	-----	-------------------------------------

Update	CMI - Collagen Meniscus Implant	3/14/2018	Stryker Endoscopy	Al-Faisaliah Medical System	FSN	https://nc
--------	---------------------------------	-----------	-------------------	-----------------------------	-----	-------------------------------------

New	Trabecular Metal Primary Hip Prosthesis	3/12/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	https://nc
-----	---	-----------	---------------------	-------------------	---	-------------------------------------

New	Versate Monofilament Mesh, 50x50 cm, Versatex	3/12/2018	Sofradim Production	Medtronic Saudi Arabia	2	https://nc
-----	---	-----------	---------------------	------------------------	---	-------------------------------------

Reusable devices

New	Endoscope washer-disinfector Soluscope Serie 4 PA	3/12/2018	Soluscope SAS	Spectromed	FSN	https://nc.mdr
-----	---	-----------	---------------	------------	-----	---

Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	ADT1018 and ADT1018-50 Flow QC Tubing – haemodialysis blood tubing Set	3/15/2018	Transonic Systems Inc	Arabian Trade House Est.	1	https://ncmdr.sfda.gov.sa/ncmdr/sfda
New	PadPro Mini-Infant Multifunction Electrodes	3/14/2018	ConMed Corporation.	ProMedEx	FSN	https://ncmdr.sfda.gov.sa/ncmdr/sfda
New	QuikClot Trauma Pad	3/12/2018	Z-Medica LLC	N/A	2	A/Ca

- * 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.