



SBED Weekly Update 26-Sep-17

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 9/18/2017 to 9/21/2017
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	Distrbutor	Class	Link
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Active Implantable Devices

New	NM Implantable Pulse Generator within the Infinity and Proclaim device families	9/20/2017	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	https://nc.mdr.sfda
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Anaesthetic and respiratory devices

New	Various Disposable Catheter Mounts	9/20/2017	Mediplas Respiratory Products Sdn Bhd	N/A	2	https://nc
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Assistive products for persons with disability

New	Freedom Healthcare Quad Walkers	9/20/2017	Gainsky Pty Ltd	N/A	2	https://nc
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	M-1 Roll In System Ambulance Stretchers with Schnitzler German Safety Hooks	9/19/2017	Stryker	Al-Jeel Medical & Trading Co. LTD	2	Attached

Diagnostic and therapeutic radiation devices

New	Artis zee and Artis Q systems with software version VD11C	9/20/2017	Siemens Medical Solutions	Siemens Medical Solutions	2	https://ncmdr
New	Aurora, Caliente Aurora, PSX400, Mobile Beat Max, Mobile Beat Max MKII, Xbeam, and Hawk 500 models	9/19/2017	X-Laser Llc	N/A	2	https://ncmdr.sfdagov
New	Brilliance 64/ Ingenuity CT / Ingenuity Core / Ingenuity Core128	9/20/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://ncmdr
New	FFR LinkFFR Signal Processing Module	9/19/2017	Boston Scientific Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	https://nc
New	MetaVision ICU	9/20/2017	iMDsoft Ltd	N/A	2	A/CaV

Electro mechanical medical devices

New	Baxter Amia Automated Peritoneal Dialysis Set with Cassette	9/19/2017	Baxter Corp Canada	Baxter AG	2	https://ncmdr
New	HEMOSNOW	9/21/2017	Biom'up	N/A	FSN	A/CaV
# Update	ROSA Surgical Systems ,	9/19/2017	Zimmer Biomet	n Medical Instruments Co	2	🔗

In vitro diagnostic devices

New	DiaMed Q.C. System.	9/20/2017	ad Medical Diagnostics G	ULREHMAN AL GOSAIBI	2	A/CaV
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Lifecodes HLA-DRB1 SSO Typing Kit and HLA-DQA1/B1 Typing Kit	9/20/2017	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	2	https://ncmdr.
New	Minicap Protein 6	9/21/2017	SEBIA	Al-Zahrawi Medical Co. I	FSN	A/Ca
New	Oxoid AST Disc - Cefazidime CAZ10	9/20/2017	ThermoFisher Scientific Microbiology Perth	Fuad Abdul Jalil Al Fadhli & Sons	2	https://nc
New	Radiometer AQT90FLEX Immunoassay analyser	9/20/2017	Radiometer America Inc	Salehiya Trading Est.	2	https://nc
# New	Various VERIS Reagent Packs Used with DxN VERIS Molecular Diagnostic Systems	9/18/2017	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	2	Attac hed

Non-active implantable devices

# New	Bileaflet Mechanical Heart Valves	9/20/2017	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed
# New	Bileaflet Mechanical Heart Valves	9/20/2017	On-X Life Technologies, Inc	Al Mofadaly Trading Est.	2	Attac hed
# New	Bileaflet Mechanical Heart Valves	9/20/2017	Sorin Group	Arabian Trade House Est.	2	Attac hed
New	Firebird NXG Spinal Fixation System Decorticating Planer	9/18/2017	Orthofix	Arabian Health Care Supply Co. (AH CSC)	2	https://ncmdr.
New	Herga foot switch, a component of ROSA Surgical Device	9/19/2017	Zimmer, INC....	Medical Regulations Gate	2	https://ncmdr.
New	Impactor Handle	9/21/2017	aldemar LINK GmbH & C	him Batterjee Sons Devel	FSN	A/Ca
New	Lentis Foldable Intraocular Lenses (IOL)	9/20/2017	Oculentis	Omar Saeed Al-Amoudi Sons Co.	2	https://nc

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Preloaded hydrophobic intraocular lenses	9/21/2017	Cristalens Industrie	N/A	FSN	https://nc

Ophthalmic and optical devices

#	New	Z28 Cartridges	9/19/2017	Aaren Scientific Inc,	Gulf Medical Co.	2	https://nc
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Reusable devices

Update	Various Duodenoscopes	9/18/2017	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	2	https://nc
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Single-use devices

New	BD Needle 22GA 11/2in SafetyGlide	9/19/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	https://nc
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* 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.