



SBED Weekly Update 27-Nov-17

Dear,

SBED team is pleased to inform you that **31** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 11/20/2017 to 11/26/2017
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	Distributor	Class	Link
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Anaesthetic and respiratory devices

New	EO-150 Ventilator	11/22/2017	EOVE	N/A	FSN	A/Cal
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Assistive products for persons with disability

New	Wheelchair models Mio, Mio Move, Kika and Vector with delivery one-hand push handle	11/20/2017	SORG Rollstuhltechnik	N/A	FSN	https://nc.mdr
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Diagnostic and therapeutic radiation devices

New	iQ200 Series Urine Microscopy Analyzer with Barcode Reader Model NFT-2100	11/23/2017	Beckman Coulter	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr
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New	iQ-X 2.2.0	11/22/2017	Information Systems Europ	N/A	FSN	A/Cal
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Symbia Intevo 6 and 16	11/21/2017	Siemens Medical Solutions	Siemens Medical Solution	2	A/Ca\
New	Syngo. plaza..	11/26/2017	Siemens Medical Solutions	Siemens Medical Solution	2	A/Ca\

Electro mechanical medical devices

New	ComputerAssisted Surgical Device	11/22/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https
New	ComputerAssisted Surgical Device, ROSA BRAIN 3.0.0	11/22/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https://nc
New	ComputerAssisted Surgical Device..	11/26/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https
New	MEDLINE PEDI ELBOW and COUBLE SWIVEL CLOSED SUCTION CATHETER	11/22/2017	Medline Industries Inc....	Ikar Establishment	2	https://nc mdr.
New	Powerheart AED G5	11/20/2017	ardiac Science Corporatio	mmed Binmahfouz Tradir	FSN	A/Ca\

In vitro diagnostic devices

New	ABX Pentra 400, Pentra C400	11/20/2017	Horiba ABX SAS	Abdulrauf Ibrahim Batterjee & Bros.	FSN	https
Update	Alinity i Processing Module	11/26/2017	Abbott	Medical supplies & Services Co.Ltd	FSN	https
New	BD Phoenix PMIC107	11/26/2017	ecton Dickinson & Co. (B	Becton Dickinson B.V.	2	A/Ca\
New	CELL-DYN Ruby	11/22/2017	Abbott	upplies & Services Co.Ltd	FSN	A/Ca\
New	Dimension Vista LOCI 8 Calibrator.	11/20/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Thermo Scientific Remel Shigella sonnei (Phases 1&2) Agglutinating Serum	11/26/2017	Thermo Fisher Scientific Inc.	Medical supplies & Services Co.Ltd Mediserv	FSN	https://nc

Non-active implantable devices

New	Anaconda Longer Leg Iliac Stent Graft System	11/20/2017	Terumo Cardiovascular Systems Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https
New	Bone Cement and Optipac	11/20/2017	Zimmer, INC....	Medical Regulations Gate	FSN	A/Ca
New	ComputerAssisted Surgical Device.	11/26/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	https
New	Cordis S.M.A.R.T.® Flex Vascular Stent System.	11/26/2017	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	https
New	iBalance(R) UKA, Femoral Cemented, Size 3, Left Medial/Right LATERAL	11/21/2017	Arthrex Inc	Al Amin Medical Instruments Co. Ltd.	2	https://nc
New	LEGION LWEDGE	11/21/2017	Smith & Nephew inc	Smith & Nephew inc	2	A/Ca
New	LEGION LWEDGE.	11/22/2017	Smith & Nephew inc	Smith & Nephew inc	2	A/Ca
New	Persona Partial Knee Impactor Pad.	11/20/2017	Zimmer, INC....	Medical Regulations Gate	FSN	https
New	Regard Custom Surgical Pack	11/26/2017	Resource Optimization & Innovation LlC	N/A	2	https
New	TRIGEN INTERTAN 10S	11/21/2017	Smith & Nephew inc	Smith & Nephew inc	2	A/Ca

Ophthalmic and optical devices


New	ACUVUE OASYS, ACUVUE ADVANCE, 1-DAY ACUVUE MOIST for Astigmatism	11/20/2017	Johnson & Johnson Vision Care	Allied Medical International	FSN	https://nc.mdr
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Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Transfer/Gait Belt	11/26/2017	Medline Industries Inc...	Ikar Establishment	2	A/CA

Single-use devices

New	HARVEST(R) TERUMOBCT, BMAC3007 Bone Marrow Procedure Pack	11/22/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	https://ncmdr
Update	ICU Medical Intravenous Sets with Stopcocks	11/22/2017	ICU Medical, Inc	AL-KAMAL Import	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.