



## SBED Weekly Update

13-Mar-18

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 3/5/2018 to 3/11/2018  
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
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**Anaesthetic and respiratory devices**

#	New	Aquilon Series Nebulizers ,	3/5/2018	AFP Medical	N/A	2	<a href="#">Attac hed</a>
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**Diagnostic and therapeutic radiation devices**

	New	Fluoroscopic XRay Systems	3/7/2018	Toshiba	N/A	2	<a href="https://nc">https://nc</a>
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#	New	ProteusONE and ProteusPLUS Proteus 235 Proton Therapy Systems	3/5/2018	Ion Beam Applications S.A.	N/A	2	<a href="#">Attac hed</a>
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	New	UST5550R Ultrasound Transducer,	3/6/2018	Hitachi America, Ltd.	N/A	2	<a href="https://nc">https://nc</a>
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**Electro mechanical medical devices**

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	MYO/Punch; A&E Surgical Punch	3/6/2018	Alto Development Corp	N/A	2	<a href="https://nc">https://nc</a>
New	Ultra Renew, Truth Renew, Ultra Renew Plus, Truth Renew Plus	3/6/2018	Accord Media, LLC	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
New	Ultrafilter U9000 ,	3/8/2018	Baxter Corp Canada	Baxter AG	FSN	<a href="A/Ca">A/Ca</a>

### In vitro diagnostic devices

New	Artisan.	3/6/2018	Dako Denmark A/S	Al-Zahrawi Medical Co. I	FSN	<a href="A/Ca">A/Ca</a>
New	BD OneFlow B-CLPD T1	3/6/2018	Becton Dickinson & Co. (BE	Becton Dickinson B.V.	FSN	<a href="A/Ca">A/Ca</a>
Update	IMMULITE/IMMULITE 1000 IMMULITE 2000/IMMULITE 2000 XPi Assays ,	3/7/2018	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	2	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a>
New	IMTEC-β2-Glycoprotein I-Antibodies IgG	3/8/2018	HUMAN Gesellschaft für Biochemica und	Arabian Trade House Est.	FSN	<a href="https://nc">https://nc</a>
New	Lipase assay on RX instruments	3/6/2018	Randox Laboratories Ltd.	Bio Standards	FSN	<a href="https://nc">https://nc</a>
New	VITROS DAT Performance Verifier	3/11/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	<a href="https://nc">https://nc</a>
New	Wiener Lab CHAGATEST ELISA RECOMBINANTE V. 3.0	3/11/2018	Wiener Laboratories	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>

### Non-active implantable devices

New	AIM Tibial Nail	3/7/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	<a href="A/Ca">A/Ca</a>
New	Concorde Lift	3/7/2018	DePuy Ireland UC	Johnson Medical Saudi Ar	2	<a href="A/Ca">A/Ca</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	CORAIL Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12	3/7/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	FSN	<a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a>
Update	Cordis S.M.A.R.T.® Flex Vascular Stent System.	3/7/2018	Cordis Corporation	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="https://nc">https://nc</a>
New	INNEX TIB INSERT FIXUC L112.5 and Modular Bipolar	3/7/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
New	ORTHOPEDIC MANUAL SURGICAL INSTRUMENT	3/6/2018	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	2	<a href="https://nc">https://nc</a>
New	OTTO BOCK Kenevo knee joints	3/6/2018	Otto Bock Healthcare Products GmbH	Al Gaim Comm. Est.	2	<a href="https://nc">https://nc</a>
# New	SpF Implantable Spinal Fusion Stimulators and EBI OsteoGen Implantable Bone Growth Stimulators	3/5/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	<a href="#">Attac hed</a>
New	staple, implantable, Endo GIA	3/11/2018	Medtronic SA	Medtronic Saudi Arabia	2	<a href="https://nc">https://nc</a>
New	StrykeFlow 2 suction/irrigator, STRYKER WEDGE, ACL DISPOSABLE , STRYKER CASSETTE PUMP	3/7/2018	Stryker Communications	Al-Faisaliah Medical System	2	<a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a>
# Update	VEGA PS TIBIA-PROBE- /PRÄPARIERPLAT.T4	3/5/2018	Aesculap	Gulf Medical Co.	FSN	<a href="#">Attac hed</a>

### Reusable devices

New	HACTIV Calcar reamers	3/8/2018	Evolutis	N/A	2	<a href="#">A/CaV</a>
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### Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	HP xxx D/x/x mit Hercotherm Ring	3/7/2018	Herco Wassertechnik GmbH	Arabian Medical and Hospital Supplies Co.	FSN	<a href="https://nc">https://nc</a>
New	Multiple Medical Devices of Hemodialysis catheter and accessories	3/7/2018	Medcomp	Farabi Trading Establishment	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
New	Sterile EXACTAMED Oral Liquid Dispenser	3/6/2018	Baxter Healthcare	Baxter AG	2	<a href="https://nc">https://nc</a>
New	Stryker Sustainability Solutions Reprocessed BW Lasso 2515 NAV eco Variable Diagnostic EP Catheters,	3/11/2018	Stryker Sustainability Solutions	N/A	2	<a href="https://nc.mdr.sfd.gov.s">https://nc.mdr.sfd.gov.s</a>
New	Tubing Set TPE LIFE 18	3/7/2018	Miltenyi Biotec GmbH	z Medical Modern Comp	FSN	<a href="A/Ca">A/Ca</a>

- \* 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.