



**SBED Weekly Update** 29-Jul-15

Dear,  
SBED team is pleased to inform you that **24** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 7/6/2015 to 7/23/2015  
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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**Anaesthetic and respiratory devices**

New	Heater-Cooler Unit HCU 40 High Voltage	7/7/2015	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	FSN	<a href="#">http://nc.mdr.</a>
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**Assistive products for persons with disability**

New	Futura, Melody, Legacy, Maxi+, Alpha, Symphony, Jazz 520, Jazz 600	7/9/2015	Invacare Corporation....	humeidan and khowaiter co.	FSN	<a href="#">http://nc.mdr.</a>
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**Dental devices**

New	3M ESPE Lava Ultimate	7/9/2015	3M ESPE Dental Products	3M company	FSN	<a href="#">A/Ca\</a>
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**Diagnostic and therapeutic radiation devices**

New	ACUSON SC2000 Ultrasound Systems..	7/9/2015	SIEMENS	Siemens Medical Solutions	2	<a href="#">http://nc.mdr.</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Philips Expression MR200 MRI Patient Monitoring System, FlexTEMP	7/9/2015	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="http://nc.mdr">http://nc.mdr</a>
New	PROCISE EZ View with Integrated Cable.	7/9/2015	Smith & Nephew Orthopaedic	Alhaya medical co.	1	<a href="http://nc">http://nc</a>
New	SOMATOM Emotion 6 & SOMATOM Emotion 16	7/6/2015	SIEMENS	Siemens Medical Solutions	2	<a href="http://nc">http://nc</a>

### Electro mechanical medical devices

New	Fibrillation cables	7/23/2015	Zethon Ltd	N/A	1	<a href="A/Ca">A/Ca</a>
New	Medline Surgical Clipper Charger base	7/23/2015	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	FSN	<a href="http://nc">http://nc</a>
New	StoneLight 30 Laser System (NS3000)	7/6/2015	New Star Lasers, Inc.	N/A	2	<a href="http://nc">http://nc</a>
New	Strattice™ Reconstructive Tissue Matrix	7/23/2015	LifeCell Corporation	N/A	FSN	<a href="http://nc">http://nc</a>

### Hospital hardware

New	Sechrist Low Profile Wheeled Stretcher	7/6/2015	Sechrist Industries Inc	Scientific & Medical Equipment House	2	<a href="http://nc">http://nc</a>
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### In vitro diagnostic devices

Update	CEFOTAXIME CT 256 WW F100.	7/9/2015	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	2	<a href="http://nc">http://nc</a>
New	Etest CEFOTAXIME CT 256	7/23/2015	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="http://nc">http://nc</a>
New	IRMA TRUPOINT	7/6/2015	LifeHealth, LLC	ading for Technical and M	2	<a href="A/Ca">A/Ca</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	VITROS 5,1 FS Chemistry System, VITROS 5,1 Refurbished, VITROS 4600 and 5600 Chemistry System..	7/6/2015	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	<a href="http://ncmdr.sfda.gov">http://ncmdr.sfda.gov</a>

### Non-active implantable devices

New	Bullet-Tip PEEKVBR/IBF System	7/6/2015	RTI Surgical, Inc	First Version Trading Est	2	<a href="http://ncmdr">http://ncmdr</a>
New	Gentle Threads Interference Screw 9x35mm Full Thread	7/6/2015	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	2	<a href="http://ncmdr">http://ncmdr</a>
New	Oxford femoral drill guide lateral IM adapter	7/9/2015	Biomet Inc	Al Amin Medical Instruments Co. Ltd.	FSN	<a href="http://ncmdr">http://ncmdr</a>
New	Reamer/Irrigator/Aspirator (RIA)	7/9/2015	Synthes Inc	Isam Economic Co.	FSN	<a href="http://ncmdr">http://ncmdr</a>
New	SCFE Drivers of the FreeGliding SCFE Screw System	7/6/2015	Pega Medical	N/A	2	<a href="http://ncmdr">http://ncmdr</a>


### Reusable devices

New	Aequalis IM Nail Targeting Jig	7/9/2015	Tornier Inc	N/A	FSN	<a href="http://ncmdr">http://ncmdr</a>
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### Single-use devices

New	Flo Gard 6201 Compatible Blood Set	7/23/2015	Baxter Healthcare	Baxter AG	FSN	<a href="http://ncmdr">http://ncmdr</a>
Update	JustRight 5mm Reload	7/9/2015	Justright Surgical, LLC	N/A	2	<a href="http://ncmdr">A/Ca\</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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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.