



**SBED Weekly Update** 14-Mar-17

Dear,  
SBED team is pleased to inform you that **36** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 3/7/2017 to 3/12/2017  
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
Update	Parker Left Double Lumen Endobronchial Tube with Parker FlexTip	3/9/2017	Parker Healthcare	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
New	Parker Left Double Lumen Endobronchial Tube with Parker FlexTip	3/9/2017	Parker Healthcare	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
New	V60 respiratory ventilator with version 2.20 software	3/8/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="https://nc">https://nc</a>

**Assistive products for persons with disability**

New	A-series lift - A625	3/7/2017	Ergosafe Products LLC	N/A	2	<a href="#">A/Ca</a>
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**Dental devices**

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Multi-unit Abutment Plus CC RP 25 mm	3/8/2017	Nobel Biocare	Al-Turki Medical Group Ltd (AMG)	FSN	<a href="https://nc">https://nc</a>

### Diagnostic and therapeutic radiation devices

New	Artis systems with wireless foot switch	3/8/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://nc">https://nc</a>
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New	Digital Linear Accelerators of type ARTISTE™, ONCOR™ and PRIMUS™ running Control Console software version 13.0.302	3/8/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda.gov.sa/Se">mdr.sfda.gov.sa/Se</a>
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New	McKesson Radiology 12.2 Picture Archive Communication System	3/7/2017	Mckesson Information Solutions LLC	N/A	2	<a href="https://nc">https://nc</a> <a href="http://mdr">mdr</a>
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New	Philips BrightView / BrightView X / BrightView XCT and BrightView X upgrade to XCT	3/9/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda.gov.s">mdr.sfda.gov.s</a>
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New	Philips Ingenuity CT system ..	3/9/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc">https://nc</a>
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### Electro mechanical medical devices

New	ConMed Hyfrecator 2000 Electrosurgical Unit and Accessory Packages containing Handpiece Sheaths	3/9/2017	ConMed Corporation.	ProMedEx	2	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda.gov.s">mdr.sfda.gov.s</a>
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New	DYONICS Battery Power Hand Pieces	3/7/2017	Smith & Nephew	Alhaya medical co.	FSN	<a href="https://nc">https://nc</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Prismaflex System, Prismaflex 4.11, Prismaflex 5.00 Row, Prismaflex 6.10 Row and Prismaflex 7.XX Row.	3/7/2017	Baxter Healthcare	Baxter AG	FSN	<a href="https://nc.mdr.sfda.gov">https://nc.mdr.sfda.gov</a>
New	SPL-G – SHOCKPULSE GENERATOR	3/9/2017	Olympus	Salehiya Trading Est.	FSN	<a href="https://nc">https://nc</a>

### Healthcare facility products and adaptations

New	Getinge HS33 Sterilisers	3/9/2017	Getinge Disinfection AB	Gulf Medical Co.	2	<a href="A/CaV">A/CaV</a>
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### In vitro diagnostic devices

New	BD Vacutainer SST II Advance Plus	3/12/2017	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	<a href="https://nc">https://nc</a>
New	CALEX Cap,	3/12/2017	HELMANN LABORATORIES	MEDICAL INNOVATIONS ES	FSN	<a href="A/CaV">A/CaV</a>
New	Liquid Cardiac Control.	3/12/2017	Randox Laboratories Ltd.	Bio Standards	FSN	<a href="A/CaV">A/CaV</a>
New	PregSure Digital Pregnancy Test & Pregsure Pregnancy Test	3/9/2017	Genesis Biotech Pty Ltd	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>
Update	Recall EliA Sample Diluent	3/12/2017	Phadia Ltd	ULREHMAN AL GOSAIBI	2	<a href="A/CaV">A/CaV</a>
New	VIDAS High Sensitive Troponin I	3/12/2017	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	<a href="https://nc">https://nc</a>
New	VITROS Chemistry Products VANC Reagent	3/9/2017	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	2	<a href="https://nc">https://nc</a>

### Laboratory equipment

New	Haemophilus Test Medium	3/9/2017	Remel Inc.	Medical supplies & Services Co.Ltd	2	<a href="https://nc">https://nc</a>
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### Non-active implantable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	StrataMR™ Adjustable Valves & Shunts .	3/9/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https://nc">https://nc</a>
New	1/3 tubular plate 3.5 / 2 and 3 round holes	3/8/2017	aap Implantate AG	Saudi Import Co. Banaja	FSN	<a href="https://nc">https://nc</a>
New	Diamond, Fierce, Ambition, Circle Collection, Lunatic, Fright, Desire and See Clear	3/9/2017	The See Clear Company	N/A	2	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda.gov.s">mdr.sfda.gov.s</a>
New	Screwdriver Shaft, hexagonal, large, diameter 3.5mm, length 165mm, for Quick Coupling	3/9/2017	DePuy International Ltd	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda.gov.s">mdr.sfda.gov.s</a>
New	VarioLoc / SM straight stern / VarioCup hip prostheses	3/8/2017	aap Implantate AG	Saudi Import Co. Banaja	FSN	<a href="https://nc">https://nc</a> <a href="http://mdr">mdr.</a>
New	various polyethylene implants	3/8/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="https://nc">https://nc</a>

### Ophthalmic and optical devices

New	Ellex Prager scleral shell for Biometry and 10MHZ Biometric A Scan Probe Kit	3/9/2017	Ellex Medical Pty Ltd	Saad Al Bashir	1	<a href="https://nc">https://nc</a> <a href="http://mdr.sfda">mdr.sfda</a>
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### Reusable devices

New	MicroAire K-Wires	3/9/2017	MicroAire Surgical Instrumer	Nogal Establishment	2	<a href="A/Ca">A/Ca</a>
New	WASSENBURG® WD440 Endoscope Washer-Disinfector	3/12/2017	WASSENBURG Medical B.V	Al Mofadaly Trading Est.	FSN	<a href="https://nc">https://nc</a> <a href="http://mdr">mdr.</a>

### Single-use devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Aerowound Combine Dressing ACD2040S, size 20cm x 40cm	3/9/2017	Aero Healthcare	N/A	2	<a href="https://ncmdr.">https://ncmdr.</a>
New	CaviWipes1 Extra Large	3/9/2017	Metrex Research, LLC	N/A	2	<a href="A/Ca">A/Ca</a>
New	multiFiltratePRO devices	3/8/2017	Fresenius Medical Care.	senius Medical Care Gmk	FSN	<a href="A/Ca">A/Ca</a>
Update	Various Products with a Blue/Polyisoprene Valve Design	3/7/2017	Cook Medical	NAFA Medical	FSN	<a href="https://ncmdr.">https://ncmdr.</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.