



**SBED Weekly Update** 03-Apr-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 3/27/2017 to 4/2/2017  
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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**Anaesthetic and respiratory devices**

New	Da Vinci® Xi EndoWrist Stapler Release Kit	4/2/2017	Intuitive Surgical Inc	Gulf Medical Co.	FSN	<a href="#">https</a>
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New	Rusch, Latex Free Robertazzi Airway	3/28/2017	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="#">https</a>
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**Assistive products for persons with disability**

New	HIGH / MID PROFILE single compartment cushion with Sensor Ready Technology	4/2/2017	ROHO Inc.	alsandross international	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
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**Dental devices**

New	Neodent 108.139 CM Exact intra oral scanbody	3/30/2017	Instradent USA, Inc.	N/A	FSN	<a href="#">https</a>
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## Diagnostic and therapeutic radiation devices

New	Artis zee systems with SW VD11 and A100 generator	4/2/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	ARTISTE MV System, Mevatron M2/Primus Mid Energy and PRIMUS HI, ONCOR" Avantgarde, ONCOR" Expression, Impression and Impression plus	3/28/2017	Siemens Medical Solutions	Siemens Medical Solutions	2	<a href="https://ncmdr.sfda.gov.sa/Se">https://ncmdr.sfda.gov.sa/Se</a>
New	Battery for defibrillator FRED easy	4/2/2017	Schiller AG	Medical supplies & Services Co.Ltd	FSN	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	Brilliance BigBore Radiology CT	3/28/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	Hitachi Echelon MRI System	3/29/2017	Hitachi Medical Corp	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	Merge Cardio with Issuer Patient ID ( IPID)	3/28/2017	Merge Healthcare Corp.	N/A	2	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	Orthosize Templating	3/28/2017	Zimmer Biomet	in Medical Instruments C	2	<a href="https://ncmdr.sfda.gov.sa/Se">A/Cal</a>
New	Robot Imager and Gantry Imager	4/2/2017	SIEMENS	Siemens Medical Solutions	FSN	<a href="https://ncmdr.sfda.gov.sa/Se">https</a>
New	Syngo.plaza Picture Archiving and communications systems	3/29/2017	Siemens Medical Solutions	Siemens Medical Solutions	2	<a href="https://ncmdr.sfda.gov.sa/Se">https://nc</a>

## Electro mechanical medical devices

New	9.6F Plastic Dignity MidSized CT port w/PreAttached Silicone Catheter	3/29/2017	Medical Components, Inc	Farabi Trading Establishment	2	<a href="https://ncmdr.sfda.gov.sa/Se">https://ncmdr.</a>
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#	New	HeartStart MRx Monitor/Defibrillators ..	3/27/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc.mdr.">https://nc.mdr.</a>
#	New	Jaundice Meters	3/27/2017	raeager Medical Systems Ir	Draeger Arabia Co. Ltd.	2	<a href="https://nc.mdr.">ttache</a>
	New	Level Sensor II Pads	3/29/2017	cardiovascular Systems Co	ULREHMAN AL GOSAIBI	2	<a href="https://nc.mdr.">A/Ca</a>
	New	NonSterile Double DIN to DIN "Y" Connector	3/29/2017	Molded Products Inc	N/A	2	<a href="https://nc.mdr.">https</a>

### Healthcare facility products and adaptations

	New	Hand Foot II	3/29/2017	National Biological Corp	N/A	2	<a href="https://nc.mdr.">A/Ca</a>
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### In vitro diagnostic devices

	New	cobas 8000 ISE module 900 / 1800, cobas c 311 / 501 / 502 / 701 / 702	3/30/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc.mdr.">https://nc</a>
	New	Legionella IFA Substrate Slide	4/2/2017	Focus Diagnostics Inc	ABDULLA FOUAD HOLDING COMPANY	2	<a href="https://nc.mdr.">https</a>

### Medical software

	New	Arial WaterResistant Pendant, model 59350	3/28/2017	Stanley Healthcare Solutions	N/A	2	<a href="https://nc.mdr.">https</a>
	New	MotoCLIP(TM) Super Elastic Fusion System	3/28/2017	Crossroads Extremity Systems Llc	N/A	2	<a href="https://nc.mdr.">https</a>

### Non-active implantable devices

#	New	BIOLOX Forte Alumina Ceramic Femoral Heads	3/27/2017	MicroPort Orthopedics	New Alnaser Medical Establishment	2	<a href="https://nc.mdr.">Attac</a>
	New	drill bit f. quick coupling; Ø3.2 x 160 / spiral In 60 / quadr. spiral / cann. / inside / Ø1,7	4/2/2017	Konigsee Implantate GmbH.	Rehab Al-Safwa	FSN	<a href="https://nc.mdr.">https://nc.mdr.</a>

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New	FLIPTACK fixation button	4/2/2017	Karl Storz GmbH & Co KG	Gulf Medical Co.	FSN	<a href="#">A/Ca\</a>
# New	Mirena Intrauterine Device Delivery Systems	3/27/2017	Bayer Consumer Care AG.	AL-KAMAL Import	2	<a href="#">Attac</a>
New	Poly Component Trial, CR	3/28/2017	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">A/Ca\</a>
New	Raindrop Near Vision Inlay	3/28/2017	Revision Optics Inc	N/A	2	<a href="#">https</a>
New	Zimmer Specific Knee, Hip and Nail Implants,	3/29/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="#">https</a>

### Ophthalmic and optical devices

New	LipiFlow	3/29/2017	Tearscience, Inc	N/A	2	<a href="#">A/Ca\</a>
New	lithomy basket series "Easy-Catch"	4/2/2017	MTW-Endoskopie	N/A	FSN	<a href="#">https</a>


### Reusable devices

New	CytoChex BCT	3/29/2017	Streck	N/A	2	<a href="#">A/Ca\</a>
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### Single-use devices

New	NC Trek RX Coronary Dilatation Catheter , NC Traveler RX Coronary Dilatation Catheter and NC Tenku RX PTCA Balloon Catheter	3/27/2017	Abbott	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a>
# New	Various Hypodermic Needles	3/27/2017	Nipro Corp .	Arabian Medical and Hospital Supplies Co.	2	<a href="#">Attac</a>
New	various kits containing ACDA	4/2/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	<a href="#">https</a>

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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.