



**SBED Weekly Update** 28-Mar-17

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 3/20/2017 to 3/26/2017  
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**

#	Data Type	MedicalDevice	Post Date	Manufacturer	Distributor	Class	Link
	New	CareFusion Patient Breathing Circuits	3/26/2017	Vyaire Medical	N/A	2	<a href="#">Attac</a>
	New	Arkon Anesthesia Delivery System	3/21/2017	Del Mar Reynolds Medical, Ltd.	N/A	2	<a href="#">https</a>
	New	Bivona TTS (Tight to Shaft) Pediatric Tracheostomy Tube	3/21/2017	Smiths Medical International Limited	almdar medical Est.	2	<a href="#">https://nc</a>
	New	HARTMANN VivanoTec / ATMOS S 042 NPWT	3/23/2017	PAUL HARTMANN	ABDULREHMAN AL GOSAIBI GTB	FSN	<a href="#">https</a>
	New	nsive care ventilators elisa 600, elisa 800 and elisa 800	3/23/2017	SALVIA medical GmbH & Co. KG	N/A	FSN	<a href="#">https://nc</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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### Assistive products for persons with disability

#	New	Carina Mobile Lifts ,	3/21/2017	Handicare Ltd	Al Safwa Dimensions	2	<a href="#">ttache</a>
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### Diagnostic and therapeutic radiation devices

#	New	IQon Spectral Computed Tomography Systems ,	3/20/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="#">Attac</a>
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	New	ProteusPLUS.	3/23/2017	IBA Dosimetry GmbH	I-Faisaliah Medical System	FSN	<a href="#">A/Ca</a>
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	New	Toshiba Kalare DREXKL80, Ultimax DREXULT80	3/21/2017	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	<a href="#">https://nc</a>
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	Update	Toshiba Kalare DREXKL80, Ultimax DREXULT80	3/21/2017	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	<a href="#">https://nc</a>
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	New	Vivid Ultrasound ,	3/20/2017	GE Healthcare	GE Healthcare	FSN	<a href="#">A/Ca</a>
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### Electro mechanical medical devices

#	Update	AK 98, 230V, Bio	3/21/2017	Gambro Lundia AB	Baxter AG	FSN	<a href="#">ttache</a>
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	New	DBS Lead Depth Stop	3/20/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="#">A/Ca</a>
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	New	PENTAX Medical ED-3490TK Duodenoscope and inspection of all PENTAX Duodenoscopes	3/23/2017	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="#">https://nc mdr. sfda.</a>
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#	New	ROSA Brain and ROSA Spine Surgical Systems	3/26/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	<a href="#">Attac</a>
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	New	Sorin Group perfusion system – Heater-cooler 1T, Heater-cooler 3T and FlexTherm devices	3/22/2017	Sorin	Arabian Trade House Est.	FSN	<a href="#">https://nc mdr.</a>
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### In vitro diagnostic devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	DIASTAT ANA ELISA Reagents	3/20/2017	Euro Diagnostica	Saudi Import Co. Banaja	2	<a href="#">Attac</a>

### Medical software

# New	Custom Glenoid Shells and Proximal Humeral Replacements	3/21/2017	Stanmore Implants Worldwide Ltd	N/A	2	<a href="#">Attac</a> <a href="#">hed</a>
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### Non-active implantable devices

New	Guide Wire	3/21/2017	Acumed LLC	N/A	2	<a href="#">A/Ca\</a>
New	iASSIST validation tool	3/23/2017	Zimmer inc	im M. Al-Mana & Bros. C	FSN	<a href="#">A/Ca\</a>

### Single-use devices

# New	7 Fr Prelude Short Sheath Introducers	3/20/2017	Merit Medical Systems Inc	Majal Care for Trading Est.	2	<a href="#">Attac</a>
# New	Absorbable Hemostats ,	3/21/2017	CuraMedical BV	al Medical Products Co. L	2	<a href="#">ttache</a>
New	Easyderm wipes .	3/26/2017	Welcare Industries Spa	Maintenance Co. For Tech	FSN	<a href="#">A/Ca\</a>
Update	Vygon	3/21/2017	Vygon UK Ltd	el Medical & Trading Co.	FSN	<a href="#">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.