



**SBED Weekly Update** 09-Oct-17

Dear,  
SBED team is pleased to inform you that **50** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 10/2/2017 to 10/8/2017  
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	IntelliVue Information Centers, Monitors	10/5/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	<a href="https://nc">https://nc</a>

**Active Implantable Devices**

Update	Platinum Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	10/2/2017	Sorin Group	Arabian Trade House Est.	FSN	<a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a>
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**Anaesthetic and respiratory devices**

New	Knee Chest Device	10/2/2017	Merivaara	pplies & Services Co.Ltd	FSN	<a href="#">A/Ca</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	LMA(TM) MADgic(TM) LaryngoTracheal Mucosal Atomization Devices	10/2/2017	Teleflex Medical .	Saudi Medical Services SMS	2	<a href="https://nc.mdr">https://nc.mdr</a>

### Dental devices

New	Endosseous Dental Implant Accessories	10/2/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="https://nc">https://nc</a>
New	Swish DuoGrip Healing Collar	10/5/2017	Implant Direct LLC	N/A	2	<a href="https://nc">https://nc</a>

### Diagnostic and therapeutic radiation devices

New	AIRO Mobile CT Scanner.	10/2/2017	Mobius Imaging, LLC	el Medical & Trading Co.	FSN	<a href="A/CaV">A/CaV</a>
New	ERGO++ and ERGO Localizer	10/8/2017	Elekta Inc	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>
New	IntelePACS InteleViewer ,	10/5/2017	elerad Medical Systems In	N/A	2	<a href="A/CaV">A/CaV</a>
New	Monitor / Defibrillator DEFIGARD Touch7	10/8/2017	Schiller AG	Medical supplies & Services Co.Ltd	FSN	<a href="https://nc">https://nc</a>
New	Multiple Artis systems ,	10/5/2017	SIEMENS	iemens Medical Solution.	2	<a href="A/CaV">A/CaV</a>
# New	Radiation Oncology Products ,	10/4/2017	SIEMENS	Siemens Medical Solutions	2	<a href="Attached">Attached</a>
New	SOMATOM go.Up and SOMATOM go. Now	10/5/2017	SIEMENS	Siemens Medical Solutions	2	<a href="https://nc">https://nc</a>

### Electro mechanical medical devices

New	Alaris / Asena GS, GH, CC, TIVA, PK, Syringe Pump	10/5/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	FSN	<a href="https://nc.mdr">https://nc.mdr</a>
New	Auriga XL 4007 Laser System	10/5/2017	Boston Scientific	Gulf Medical Co.	2	<a href="https://nc">https://nc</a>

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New	Auriga XL 4007 Laser System ,	10/5/2017	Boston Scientific	Gulf Medical Co.	2	<a href="https://nc">https://nc</a>
New	BOMImed Disposable Fiber Optic Medium Laryngoscope Handle	10/2/2017	BOMImed Inc	N/A	2	<a href="https://nc.mdr">https://nc.mdr.</a>
# New	Endoscopic Ultrasonic Probes	10/4/2017	FUJIFILM Corporation	Al-Jeel Medical & Trading Co. LTD	2	<a href="Attached">Attached</a>
Update	Model 3200 S-ICD programmer	10/5/2017	Boston Scientific Cardiac Rhythm	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc">https://nc</a>
Update	schaerer arcus	10/2/2017	Schaerer Medical AG	ATTIEH MEDICO LTD	FSN	<a href="A/Ca">A/Ca</a>

### Hospital hardware

New	Progressa Bed System ,	10/5/2017	Hill Rom Inc	Medical regulations gate	2	<a href="A/Ca">A/Ca</a>
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### In vitro diagnostic devices




New	AutoCheck5	10/2/2017	Radiometer America Inc	Salehiya Trading Est.	2	<a href="A/Ca">A/Ca</a>
New	BIOPHEN ARIXTRA CONTROL PLASMA	10/2/2017	HYPHEN BioMed SAS	N/A	FSN	<a href="https://nc">https://nc</a>
New	Eppendorf Reference 2	10/8/2017	Eppendorf AG	CARE DRUG STORE COM	FSN	<a href="A/Ca">A/Ca</a>
New	Free Testosterone ELISA Kits	10/8/2017	DIAGNOSTICS BIOCHEM CANADA INC.	ABDULLA FOUAD HOLDING COMPANY	FSN	<a href="https://nc">https://nc</a>
New	MultiCare Analyzer/ Lumiratek C	10/8/2017	SD BIOSENSOR	Tabaeb-Najd Trading Establishment	FSN	<a href="https://nc">https://nc</a>

### Medical software

New	Philips Network, Cisco Adaptive Security Appliance (ASA) 5506 firewall	10/2/2017	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="https://nc.mdr.sfda">https://nc.mdr.sfda.</a>
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### Non-active implantable devices

#	Update	Cobalt Bone Cement	10/5/2017	Zimmer inc	m M. Al-Mana & Bros. Co	2	<a href="#">Attache</a>	
#	New	Conformable GORE TAG Thoracic Endoprosthesis Devices	10/2/2017	W.L. Gore & Associates Inc.	Med Surg Supplies	1	<a href="#">Attached</a>	
	New	Delta cup beater-positioner-aligner	10/2/2017	Limacorporate S.p.a.	N/A	FSN	<a href="https://nc">https://nc</a>	
	New	Drill Bit QuickConnect	10/2/2017	Zimmer, INC....	Medical Regulations Gate	2	<a href="#">A/Ca\</a>	
	New	expanSys metamys inlays	10/2/2017	Mathys Ltd Bettlach	Isam Economic Co.	FSN	<a href="#">A/Ca\</a>	
#	Update	Gap Endo-Exo Medullary Nail Drivers	10/4/2017	Pega Medical	N/A	2	<a href="#">Attached</a>	
	New	GMK Sphere and GMK Primary PS Inserts	10/5/2017	Medacta International SA	N/A	FSN	<a href="https://nc">https://nc</a>	
	New	Head Fixation Device (HFD100) Starburst adaptor thumb screw	10/2/2017	Deerfield Imaging	N/A	2	<a href="https://nc.mdr">https://nc.mdr</a>	
	New	proSA Tool Set	10/8/2017	toph Miethke GmbH & Co	cellent Care Medical Co. L	FSN	<a href="#">A/Ca\</a>	
	New	SAFE-CUT	10/8/2017	EX Medical Technologies	nights Of Technology. Es	FSN	<a href="#">A/Ca\</a>	
	New	Specific Hip and Trauma instruments	10/5/2017	Zimmer, INC....	Medical Regulations Gate	FSN	<a href="https://nc">https://nc</a>	

### Ophthalmic and optical devices







	New	PROVEO 8	10/2/2017	Leica Microsystems Inc.	I-Faisaliah Medical Syster	FSN	<a href="#">A/Ca\</a>	
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### Reusable devices


	New	IVEA	10/2/2017	Firefly Medical, Inc	N/A	2	<a href="#">A/Ca\</a>	
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## Single-use devices

#	New	Ascenda Intrathecal Catheters and Ascenda Revision Kits	10/3/2017	Medtronic SA	Medtronic Saudi Arabia	2	<a href="#">Attac hed</a>	
#	Update	CADD(R) Medication Cassette with clamp and female Luer	10/5/2017	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2	<a href="#">Attac hed</a>	
#	New	ICU Medical Intravenous Sets with Stopcocks	10/3/2017	ICU Medical, Inc	AL-KAMAL Import	2	<a href="#">Attac hed</a>	
#	New	INTRALIPID 20% IV Fat Emulsions in 100 mL Plastic Containers	10/4/2017	Baxter Healthcare	Baxter AG	2	<a href="#">Attac hed</a>	
	New	Infusion Controller STAT 2	10/8/2017	ACCURA Medizintechnik GmbH	Heritage Medical Company	FSN	<a href="https://nc">https://nc</a>	
#	New	Max-Core Disposable Core Biopsy Instruments	10/3/2017	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	<a href="#">Attac hed</a>	
#	Update	REVOLVE Advanced Adipose Systems	10/5/2017	Allergan services international Limited	Cigalah Group	2	<a href="#">Attac hed</a>	
	New	SECURE(R) 100mL EMPTY VINYL CONTAINER With 2 Ports	10/2/2017	The Metrix Co	N/A	2	<a href="https://nc mdr">https://nc mdr</a>	
	Update	SPY-PHI Drapes	10/2/2017	lovadaq Technologies Inc	Arabian Trade House Est.	2	<a href="#">A/Cal</a>	
#	New	Vacutainer Barricor Lithium Heparin Plasma Blood Collection Tubes	10/3/2017	BD Biosciences	Becton Dickinson B.V.	2	<a href="#">Attac hed</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.