



SBED Weekly Update 25-Aug-15

Dear,
SBED team is pleased to inform you that **45** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 8/17/2015 to 8/23/2015
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
New	adjustable positioning elements	8/17/2015	MAQUET Inc	Gulf Medical Co.	FSN	http:
New	HQD Flow Probe	8/20/2015	Transonic Systems Inc	N/A	FSN	A/Ca\
New	Hyperventilation mask	8/20/2015	ngchang Medical Instrum	Jama Medical Co. Ltd.	FSN	A/Ca\
New	M6 service head	8/20/2015	ndal medical system Gmb	N/A	FSN	A/Ca\
Update	Puritan Bennett™ 980 Series Ventilator System For Universal and Neonatal Models	8/20/2015	Covidien LLC	Covidien AG	FSN	http://nc.mdr.

Assistive products for persons with disability

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	wheelchair Quickie Jive UP	8/20/2015	Sunrise Medical	Al-Enayah Company	FSN	A/Ca\

Diagnostic and therapeutic radiation devices

Update	CT LightSpeed 16	8/18/2015	GE Healthcare	GE Healthcare	2	A/Ca\
New	Digital Linear Accelerators/Update for the syngo RT Therapist™ software and the Control Console software	8/20/2015	Siemens Medical Solutions	Siemens Medical Solutions	FSN	http://nc.mdr.sfda
New	DRX Evolution Systems w/Premium and Full Featured Wall stands	8/20/2015	Carestream Health Inc Div Onex Corp	Bio Standards	FSN	http://nc
New	ExacTrac 6.0 Patient Positioning System	8/20/2015	Brainlab AG	Al-Jeel Medical & Trading Co. LTD	FSN	http

Electro mechanical medical devices

New	iovera 155 Smart Tip	8/18/2015	Myoscience Inc	N/A	2	A/Ca\
New	Philips G60 patient monitor	8/20/2015	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	FSN	http
New	SUREFLUX 25UX LC GA	8/20/2015	Nipro Corp .	Medical and Hospital Sup	FSN	A/Ca\
New	TurnPike Spiral and TurnPike Gold Catheters	8/17/2015	Vascular Solutions Inc	N/A	1	http

Healthcare facility products and adaptations

New	CLINIPOD (sterile normal saline topical irrigation solution)	8/20/2015	Amanta Healthcare	N/A	FSN	http://nc
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In vitro diagnostic devices

New	ARCHITECT c8000 System	8/18/2015	Abbott	bbott Diagnostics Divisio	2	A/Ca\
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	cobas 6800 / 8800 systems	8/20/2015	Roche Diagnostics Ltd	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http://
Update	cobas b 221 <5>, cobas b 221 <6>, S3 Fluid Pack A	8/20/2015	Roche Diagnostics Ltd	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http://nc
New	Extension Set	8/23/2015	MDi TUTA Healthcare Pty L	N/A	2	A/CaV
New	Fluitest CREA PAP and for all products based on the "Trinder Reaction"	8/17/2015	Analyticon Biotechnologies AG	N/A	FSN	http://nc
New	Folate Ascorbic Acid	8/20/2015	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	1	A/CaV
New	FreeStyle Optium Neo Blood Glucose and Ketone Monitoring System	8/20/2015	Abbott Diabetes Care Div Abbott Laboratories Inc	Abbott Diagnostics Division	2	http://nc.mdr
New	LABGEOPT Lipid Test 5S and LABGEOPT Lipid Test 5	8/17/2015	Samsung Electronics	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	http://nc
New	NEFA FS	8/20/2015	ys Diagnostic Systems Gr	N/A	FSN	A/CaV
New	Paragon Laboratory Management	8/20/2015	Mckesson Medical Imaging Group	N/A	2	http://
New	ST AIA-PACK 25-OH Vitamin D CALIBRATOR SET	8/17/2015	Tosoh Corporation	ABDULLA FOUAD HOLDING COMPANY	FSN	http://nc
New	TruCal Lp (a) 21 calibrator	8/20/2015	ys Diagnostic Systems Gr	N/A	FSN	A/CaV

Non-active implantable devices

New	Aortic Punch products	8/17/2015	ternational Biophysics Co	N/A	FSN	A/CaV
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Cochlear Nucleus Sterile Silicone Template	8/18/2015	Cochlear AG	ABDULREHMAN AL GOSAIBI GTB	2	http://
New	Femoral Cut Block	8/20/2015	Encore Medical, Lp	Al Ewan Medical Compan	2	A/Ca
New	InjectionPlasty 1.0	8/20/2015	Skeletal Kinetics, Llc	N/A	2	A/Ca
New	LEXA femoral components	8/20/2015	C2F IMPLANTS	N/A	FSN	A/Ca
New	Locking Screw Diameter 3.5mm, Length 14mm	8/20/2015	Synthes Inc	Isam Economic Co.	FSN	http://
New	the Intrauterine Contraceptives Mirena and Nova T 380	8/20/2015	Bayer Healthcare LLC..	Scientific & Medical Equipment House	FSN	http://nc
New	TRIGEN 8/7 mm x 24 cm Humeral Nail	8/20/2015	Smith & Nephew Orthopaedic	Alhaya medical co.	FSN	http://

Ophthalmic and optical devices


New	Hypromol eye drops BP (sterile hydroxy propyl methyl cellulose (HPMC) Eye drops)	8/20/2015	Amanta Healthcare	N/A	FSN	http://ncmdr
New	Insufflation hose, silicone	8/20/2015	Xion GmbH	Attieh Medico Ltd.	FSN	A/Ca
New	MANI Trocar Kit	8/17/2015	MANI, INC.	basar For Medical Suppli	FSN	A/Ca
New	MicroSil IF and MicroSil IFT intraocular lenses	8/17/2015	HumanOptics AG	N/A	FSN	http://
New	Proximal Lighting Insert	8/20/2015	Richard Wolf GmbH	el Medical & Trading Co.	FSN	A/Ca
New	the rollator TOPRO Troja 2G	8/20/2015	TOPRO Industri AS	N/A	FSN	http://

Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	EOPA Arterial Cannula	8/17/2015	Medtronic Inc	Gulf Medical Co.	FSN	A/Ca\

Single-use devices

New	AngioJet Thrombectomy Sets	8/20/2015	Boston Scientific Ltd	FAROUK, MAAMOUN TAMER & COMPANY	FSN	http:
New	EKOS EkoSonic Endovascular System	8/18/2015	EKOS Corp	N/A	2	http:
New	Ipswich ANTT adult cannulation pack	8/20/2015	Vygon UK Ltd	Al-Jeel Medical & Trading Co. LTD	FSN	http:

- * 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.