



SBED Weekly Update 18-Sep-18

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 9/10/2018 to 9/16/2018
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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Active Implantable Devices

#	New	HeartWare Ventricular Assist Device Controllers	9/10/2018	Medtronic SA	Medtronic Saudi Arabia	FSN		
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Anaesthetic and respiratory devices

New	EverFlo (Oxygen Concentrator)	9/13/2018	Philips Burton	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc	
New	Organ Care System (OCS) Heart Console, OCS Lung Console, OCS Liver Console	9/16/2018	TransMedics	N/A	FSN	https://nc mdr. sfda.	

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	power supply units for the sleep therapy devices SOMNObalance, SOMNOsoft 2, prisma SOFT and prisma SMART	9/16/2018	Lowenstein Medical GmbH &Co.KG	Bio Standards	FSN	https://nc.mdr.sfd.a.gov.s	

Assistive products for persons with disability

New	ORT 353D, ORT 353C and ORT 01G Orthopaedic Extensions	9/12/2018	STERIS Corporation.	Al-Faisaliah Medical System	FSN	https://nc.mdr.	
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New	SLK Varilymph 12 Pro	9/16/2018	SLK Medical GmbH	N/A	FSN	A/Cal	
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Diagnostic and therapeutic radiation devices

New	Accelerator a3600	9/12/2018	Abbott	pplies & Services Co.Ltd	FSN	A/Cal	
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New	Accelerator APS	9/12/2018	Abbott	pplies & Services Co.Ltd	FSN	A/Cal	
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New	AIRO Mobile CT Scanner (model # MobiCT-32)	9/16/2018	Mobius Imaging, LLC	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc	
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New	Dash 3000/4000/5000, Solar 8000M/i, and Solar 9500 patient monitors	9/12/2018	GE Healthcare	GE Healthcare	FSN	https://nc.mdr.	
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# New	RADREX-i Digital Radiography System Wireless Flat Panel Detectors	9/10/2018	Toshiba Medical Systems Corporation	Gulf Medical Co.	FSN		
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In vitro diagnostic devices

# New	ARCHITECT ICT Modules	9/10/2018	Abbott Laboratories Inc	pplies & Services Co.Ltd	FSN		
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Cybersecurity updates in Accu-Chek® Inform II system, cobas h 232 POC system, CoaguChek® Pro II system, CoaguChek® XS Plus / XS Pro systems	9/12/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc.mdr.sfd.a.gov.sa/Secure/	

New	Lot-to-Lot Variability When Using Dimension® Lipase (LIPL)	9/13/2018	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc.mdr.	
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Medical software

New	MetaVision Suite, Clinical Information System	9/10/2018	iMDsoft Ltd	N/A	FSN	https://nc.	
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Non-active implantable devices

New	611P CT Lucia Intraocular Lenses +11.5 D	9/16/2018	Carl Zeiss Meditec Inc	Gulf Medical Co.	FSN	https://nc.	
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# New	Broken 2.7 CO Trephines	9/10/2018	Acumed LLC	Bio Standards	FSN		
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New	Cardioband Mitral Reconstruction System IFU	9/16/2018	Edwards Lifesciences	Arabian Health Care Supply Co. (AHSCS)	FSN	https://nc.mdr.	
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# New	CyPass Micro-Stents	9/10/2018	Alcon Laboratories Inc.	n Medical Instruments Co	FSN		
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New	HipLOC System Plate Barrel	9/16/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https://nc.	
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New	Osteosynthesis, trauma implant, Drill CS 2.7/3.5, ø2.7, L 130, quick coupling, sterile	9/16/2018	aap Implantate AG.	Cure Development International Ltd	FSN	https://nc.mdr.sfd.a.	
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New	Zimmer Natural Nail System Tibial Nail – Yellow 8.3 mm	9/16/2018	Zimmer Biomet, Inc.	Isam Economic Co.	FSN	https://nc.mdr.	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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Reusable devices

New	CX1020, CX2020, PS5xxx sterilisers	9/16/2018	Miele	Scientific & Medical Equipment House	FSN	https://nc	
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Single-use devices

New	ECO BATH WIPES with 2% w/v Chlorhexidine Gluconate Solution	9/16/2018	CareNow Medical Pvt Ltd	Cure Development International Ltd	FSN	https://nc.mdr	
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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.