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Kingdom of Saudi Arabia
Saudi Food & Drug Authority



المملكة العربية السعودية
الهيئة العامة للأدوية والدواء

Medical Devices Sector

Executive Department of Surveillance & Biometrics

قطاع الأجهزة والمنتجات الطبية

الإدارة التنفيذية للرقابة والقياسات الحيوية

SBED Weekly Update

10-Jul-18

Dear,

SBED team is pleased to inform you that **64** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/2/2018 to 7/8/2018
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



Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
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Active Implantable Devices

New	Merlin PCS Programmer Software	7/2/2018	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	2	A/Cal	
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Anaesthetic and respiratory devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	AMBU Ultraseal II Anaesthetic Mask	7/3/2018	Ambu Inc	ABDULREHMAN AL GOSAIBI GTB	2	A/CaV	
New	da Vinci Surgical System	7/3/2018	Intuitive Surgical Inc	Gulf Medical Co.	FSN	A/CaV	
New	SERVOX Silberkanüle	7/3/2018	Servona GmbH	N/A	FSN	A/CaV	
Assistive products for persons with disability							
New	CARLO Patient Lift	7/8/2018	BEKA Hospitec GmbH	N/A	FSN	A/CaV	
New	Earmoulds in use with children under 36 months	7/3/2018	Starkey Laboratories	N/A	2	https	
New	Zippie Zone Wheelchair	7/3/2018	Sunrise Medical	Al-Enayah Company	2	A/CaV	
Diagnostic and therapeutic radiation devices							
New	Enterprise Imaging for Radiology ,	7/5/2018	AGFA Corp.	Gulf Medical Co.	FSN	A/CaV	
New	Brilliance 64, Brilliance CT BigBore, Brilliance iCT, Brilliance iCT SP, Ingenuity Core, Ingenuity Core128, Ingenuity CT, and IQon Spectral CT ,	7/5/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https://nc.mdr.sfda.gov.s	
New	DEFIGARD TOUCH7	7/5/2018	Schiller AG	ical supplies & Services Co.Ltd Med	FSN	A/CaV	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	MobileDiagnost wDR..	7/5/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	A/CaV	
# New	Patient Supports for Stitching ,	7/4/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	A/CaV	
New	Philips Ingenuity Core128/Elite China 728324	7/2/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https	
New	Proton Therapy System Proteus 235 (brand names: Proteus Plus and Proteus ONE)	7/2/2018	Ion Beam Applications S.A.	N/A	2	https	
# New	RADREX-I Wireless X-Ray Detector Systems ,	7/4/2018	Canon Inc	N/A	2	Attac	
New	RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2), RayStation 7 (RayPlan 7) and RayStation 8A (RayPlan 8A)	7/5/2018	RaySearch Laboratories AB	N/A	FSN	https://nc.mdr.sfda	
New	SureSigns VS & VM Monitors, and View Station (VSV)	7/5/2018	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	https	
New	Synapse Cardiovascular (CV) Software ,	7/3/2018	FUJIFILM Medical Systems	OUK, MAAMOUN TAMER & COMP/	2	A/CaV	
New	verschiedene MRT-Systeme	7/3/2018	GE Medical Systems	GE Healthcare	FSN	A/CaV	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	VISERA ELITE II VIDEO SYSTEM CENTER OLYMPUS	7/5/2018	Olympus Winter & IBE GmbH	Salehiya Trading Est.	FSN	https	

Electro mechanical medical devices

New	5008 CorDiax HD-PAED option	7/5/2018	Fresenius Medical Care.	Fresenius Medical Care GmbH	FSN	A/CaV	
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New	Dermatome AN	7/2/2018	Zimmer Inc.....	Isam Economic Co.	2	A/CaV	
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# Update	Dermatome AN	7/4/2018	Zimmer Inc.....	Isam Economic Co.	2	ttache	
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New	HLD Systems 600 Series Washer/Pasteurizer	7/2/2018	Cenorin	N/A	2	A/CaV	
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Update	Mega Power Electrosurgical Generators	7/5/2018	Megadyne Medical Products Inc	n & Johnson Medical Saudi Arabia L	2	A/CaV	
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# New	MyCareLink Patient Monitors	7/8/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	ttache	
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New	NxStage Express Fluid Warmer	7/3/2018	NxStage Medical, Inc.	REDWAN MEDICAL SERVICES	2	A/CaV	
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# New	SIGMA SPECTRUM V6 Platform Infusion Pumps ,	7/4/2018	Baxter Corp Canada	Baxter AG	2	Attac	
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# New	SureStore Endoscope Conditioning Systems	7/8/2018	Cantel Medical	N/A	FSN	ttache	
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New	THERA treatment tables ,	7/8/2018	Frei AG Aktive Reha	N/A	FSN	A/CaV	
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	Visualase Thermal Therapy Systems ,	7/4/2018	Medtronic SA	Medtronic Saudi Arabia	2	ttache	



In vitro diagnostic devices

New	ABL800	7/5/2018	Radiometer America Inc	Salehiya Trading Est.	FSN	A/Ca\	
New	ABL800..	7/5/2018	Radiometer America Inc	Salehiya Trading Est.	FSN	A/Ca\	
New	BACT/ALERT® VIRTUO® Microbial Detection System	7/5/2018	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https	
Update	FilmArray Blood Culture Identification (BCID) Panel	7/5/2018	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https	

# New	IVDD Mentype MycoDerm Lateral Flow Kits	7/4/2018	Biotype Diagnostik GmbH	N/A	2	ttache	
New	Thermo Scientific™ QMS™ Calibrator and Associated Teicoplanin Reagent	7/5/2018	Microgenics Corp.	ABDULLA FOUAD HOLDING COMPANY	FSN	https	

Non-active implantable devices




New	Ankle Arthrodesis Nail / Proximal Humeral Nail	7/3/2018	Stryker Communications	Al-Faisaliah Medical System	FSN	https	
New	Cannulated Driver Handles	7/5/2018	Trilliant Surgical Ltd	N/A	2	A/Ca\	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	CORAIL Cementless Femoral Stem HA Coated Standard Size 11 and Size 12	7/3/2018	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	FSN	https://nc	
# New	FPS Depth Gauges	7/8/2018	Ortho Solutions	N/A	FSN	ttache	
New	LEGION HK TIBIAL BASE S. 5 LEFT	7/3/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	A/CaV	
New	PALACOS® and COPAL® bone cements	7/8/2018	Heraeus Medical GmbH	Al Amin Medical Instruments Co. Ltd	FSN	A/CaV	
# New	Phoenix Femoral Nail System Antegrade Femoral Connecting Bolts ,	7/4/2018	Zimmer Inc.....	Isam Economic Co.	2	Attac	
New	QuikFlap Neuro Implants	7/2/2018	tryker Leibinger GmbH & Co.KG	Zimmo Trading Establishment.	2	A/CaV	

Ophthalmic and optical devices

New	Safety Sideport Knife	7/5/2018	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd	2	A/CaV	
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Reusable devices

# New	Drill Sleeve Guides ,	7/4/2018	ECH Medical Instrument Corpor	Al-Nozha Medical Est	2	ttache	
# New	MAYFIELD Spine Table Adapters and Various Infinity XR2 Base Units	7/8/2018	Integra LifeSciences	Bio Standards	FSN	Attac	
# New	OTE-02 Electrocardiograph Trolleys ,	7/4/2018	Fukuda Denshi	CENTRE FOR TRADING COMPANY	2	ttache	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)	
Single-use devices								
#	New	2 L MED-RIGID Disposable Rigid Suction Canisters	7/4/2018	Medline Industries Inc...	Ikar Establishment	2	Attac	
	New	26Lead Transfer Set for use with APEX Compounding System	7/5/2018	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	2	https	
#	New	Alaris Extension Sets with Microbore Tubing	7/2/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	ttache	
#	New	Aplicare Povidone Prep Pads Contained in Pro-Vent and Pulsator ABS Kits	7/8/2018	Medline Industries Inc...	Ikar Establishment	FSN	Attac	
#	New	BD 10 mL Luer-Lok Syringes ,	7/3/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	2	ttache	
	New	Cannula needle	7/5/2018	Applimed SA	N/A	FSN	A/CaV	
#	New	Degania Silicone Medline-Labeled Temperature Sensor Catheters	7/4/2018	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	2	Attac	
#	New	Disposable Tubing Sets Used with Trima Accel Automated Blood Collection Systems	7/4/2018	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	Attac	
	New	Hydraulic Ureter Dilators	7/8/2018	Teleflex Medical	Ebrahim M. Al-Mana & Bros. Co. Ltd	FSN	A/CaV	
	New	In-Line Blood Set with Filter	7/3/2018	Baxter Corp Canada	Baxter AG	1	A/CaV	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	NeoMed Enteral Feeding Tubes with EO Connectors	7/3/2018	NeoMed Inc	N/A	2	https	
New	Raucodrape camera drape 16x250 in set Kitpack	7/8/2018	Lohmann und Rauscher GmbH & Co. KG.	Medical Regulations Gate	FSN	https	
New	Safe N Simple NoSting Skin Barrier Film	7/2/2018	Safe N Simple, LLC	N/A	2	A/CA	
New	Safil Sutures ,	7/3/2018	B Braun Surgical SA	Gulf Medical Co.	2	A/CA	
# New	Tri-Flo Subglottic Suction Systems	7/4/2018	Vyair Medical, Inc..	Bio Standards	2	ttache	

* 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.