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Kingdom of Saudi Arabia  
Saudi Food & Drug Authority



المملكة العربية السعودية  
الهيئة العامة للغذاء والدواء

Medical Devices Sector  
Executive Department of Surveillance & Biometrics

قطاع الأجهزة والمنتجات الطبية  
الإدارة التنفيذية للرقابة والقياسات الحيوية

**SBED Weekly Update** 03-Jul-18

Dear,  
SBED team is pleased to inform you that **52** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 6/25/2018 to 7/1/2018  
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	EnTrust and Escudo VR/DR/AT ICDs	6/27/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="#">A/Ca</a>	
New	Percepta™ CRT-P MRI SureScan™ and Percepta™ Quad CRT-P MRI SureScan™ Pacemakers	6/27/2018	Medtronic SA	Medtronic Saudi Arabia	FSN	<a href="https://nc">https://nc</a>	

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### Anaesthetic and respiratory devices




New	CARESCAPE R860, ENGSTROM CARESTATION and ENGSTROM PRO	6/28/2018	GE Healthcare	GE Healthcare	FSN	<a href="https://nc">https://nc</a>	
Update	Equinox Relieve and Equinox Relieve II N2O/O2 Analgesic Gas Mixing and Delivery Systems	6/26/2018	O-Two Medical Technologies, Inc	Dar Al Najat Medical Tech.	2	<a href="https://nc">https://nc</a>	
Update	Fabius, Apollo & Perseus devices	6/27/2018	Draeger Medical Systems In	Draeger Arabia Co. Ltd.	FSN	<a href="A/Ca">A/Ca</a>	
New	Intersurgical Breathing Circuit 22mm, nonconductive, single patient use	6/28/2018	Intersurgical Limited	Al Hammad Medical Services	2	<a href="https">https</a>	
New	SOPHIE	6/26/2018	Fritz Stephan GmbH	N/A	FSN	<a href="A/Ca">A/Ca</a>	

### Assistive products for persons with disability

New	Treatment table with a MAX60 motor	6/27/2018	imbH Medizinische Praxis e	N/A	FSN	<a href="A/Ca">A/Ca</a>	
New	Trigo Sport	6/26/2018	Hase Bikes	N/A	FSN	<a href="A/Ca">A/Ca</a>	

### Diagnostic and therapeutic radiation devices

New	Artis Q/Pheno systems	6/27/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="A/Ca">A/Ca</a>	
Update	Artis zee/Q/Q.zen systems with Large Display DSC 5608-DC	6/28/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="https">https</a>	

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New	AXIOM Aristos MX/VX	6/26/2018	SIEMENS	Siemens Medical Solutions	FSN	<a href="#">A/Cal</a>	
# New	CardioMEMS Hospital and Patient Electronic Systems	6/27/2018	Abbott	Medical supplies & Services Co.Ltd Mediserv	2		
New	Diagnostic X-ray system GC80, GC85, GC70	6/27/2018	Samsung Electronics	Ebrahim M. Al-Mana & Bros. Co. Ltd.	FSN	<a href="#">https</a>	
# New	Model 3000 VNS Therapy Programmers	6/25/2018	LivaNova PLC	cigalah group	2		
New	ProteusPLUS and ProteusONE..	6/28/2018	Ion Beam Applications S.A.	N/A	2	<a href="#">A/Cal</a>	
New	RayStation 2.5, RayStation 3.5, RayStation 4.0, RayStation 4.3 (InverseArc 1.0), RayStation 4.5, RayStation 4.7, RayStation 4.9 (RayPlan 1), RayStation 5, RayStation 6 (RayPlan 2) and RayStation 7 (RayPlan 7)	6/27/2018	RaySearch Laboratories AB	N/A	FSN	<a href="https://ncmdr.sfd.gov.sa/Se">https://ncmdr.sfd.gov.sa/Se</a>	
New	S-SPOT, Tomo-SPOT, O-SPOT ,	7/1/2018	Beekley Corp	Bio Standards	FSN	<a href="#">A/Cal</a>	
# New	Xltek NeuroWorks Software	6/27/2018	Incorporated, DBA Excel-Te	ATTIEH MEDICO LTD	2		

### Electro mechanical medical devices

New	BioFlo PICC (NV)	6/25/2018	AngioDynamics Inc	K, MAAMOUN TAMER & COI	2	<a href="#">A/Cal</a>	
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# New	CADD-Solis VIP Ambulatory Infusion Pumps	6/27/2018	Smiths Medical ASD Inc..	MEDICARE DRUG STORE COMPANY	2		0
New	Catheter, C2 CryoBalloon" Ablation System	6/25/2018	C2 Therapeutics Inc.	N/A	2	<a href="https://nc">https://nc</a>	
# New	J-Plasma Precise 360 Handpieces	6/25/2018	Bovie Medical Corporation	Bio Standards	FSN		0
New	Maestro 4000 Cardiac Ablation System	6/27/2018	Boston Scientific Cardiac Rhythm Management	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc">https://nc</a>	
Update	PENTAX Medical ED-3490TK Duodenoscope and inspection of all PENTAX Duodenoscopes	6/25/2018	PENTAX Europe GmbH	Medical supplies & Services Co.Ltd Mediserv	FSN	<a href="https://nc">https://nc</a>	

### In vitro diagnostic devices

New	2-MET Urine ELISA Fast Track	6/26/2018	ordiagnostika Nord GmbH	N/A	FSN	<a href="A/Cal">A/Cal</a>	
New	ABX Pentra Micro ALBUMIN 2 CP	6/28/2018	Horiba ABX SAS	uf Ibrahim Batterjee & Bros. C	2	<a href="A/Cal">A/Cal</a>	
New	Alinity hq Analyzer ,	6/28/2018	Abbott	supplies & Services Co.Ltd M	FSN	<a href="A/Cal">A/Cal</a>	
New	Alinity s System ,	6/27/2018	Abbott	supplies & Services Co.Ltd M	FSN	<a href="A/Cal">A/Cal</a>	
Update	cobas omni MGP Reagent when used with cobas MPX assay (for use on the cobas 6800/8800 systems)	6/27/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https://nc">https://nc</a>	

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
New	cobas p 612 pre-analytical system (LCP1)	7/1/2018	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https">https</a>	
New	MDmulticard Basic Extended Phenotype	6/27/2018	Medion Grifols Diagnostics AG	ABDULLA FOUAD HOLDING COMPANY	FSN	<a href="https">https</a>	
# New	RAPIDLab 1200 and RAPIDPoint 400/500 Blood Gas Analyzers	6/27/2018	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	FSN		0
New	VITROS Chemistry Products Na+ Slides	6/27/2018	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	FSN	<a href="https">https</a>	

### Non-active implantable devices

New	Biomet Modular Primary Tibial Tray Implants (size 75 mm)	6/26/2018	Zimmer Biomet, Inc.	Isam Economic Co.	2	<a href="https">https</a>	
New	Drill guide for the JAWS Nitinol Staple System	6/27/2018	Paragon 28, Inc	N/A	2	<a href="https">https</a>	
New	First generation JOURNEY BCS femoral and tibial insert components	6/27/2018	Smith & Nephew inc	Smith & Nephew inc	FSN	<a href="https">https</a>	
New	Perceval Sutureless Heart Valve	6/27/2018	LivaNova PLC	cigalah group	FSN	<a href="A/Cal">A/Cal</a>	

### Reusable devices

# New	Designed for Digital and TomoSPOT Skin Markers	6/25/2018	Beekley Corp	Bio Standards	FSN		0
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	Endoscopic Cleaning Brushes	6/27/2018	Medline Industries Inc....	Ikar Establishment	2		🔒
New	Pilling(R) UNIVERSAL SHEARS	6/28/2018	Teleflex Medical .	Saudi Medical Services SMS	2	<a href="#">A/Cal</a>	
New	Trocar ENDOSPHERE	6/27/2018	Peters Surgical	Dawha Medical	FSN	<a href="#">A/Cal</a>	
<b>Single-use devices</b>							
New	Alaris / Asena GS, GH, CC, TIVA, PK, Enteral Syringe Pump	6/27/2018	Becton, Dickinson And Company	Medical Regulations Gate	FSN	<a href="#">https</a>	
New	Amalgatome SD	6/28/2018	Exsurco Medical	N/A	2	<a href="#">A/Cal</a>	
New	Arrow® HANDS-OFF® Thermodilution Catheter	6/27/2018	Arrow International Inc	Gulf Medical Co.	FSN	<a href="#">https</a>	
# New	Covidien Polysorb Braided Absorbable Sutures	6/25/2018	Medtronic SA	Medtronic Saudi Arabia	FSN		🔒
New	Graphic Case 6.5mm & 7.3mm Cannulated Screw Sets	6/26/2018	Synthes GmbH.	Johnson & Johnson Medical Saudi Arabia	2	<a href="#">https</a>	
# New	Hypodermic NEOLUS Needles	7/1/2018	Terumo Europe N.V	3DULREHMAN AL GOSAIBI G	FSN	t	🔒

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected? (Yes/No)
# New	Povidone-Iodine Presaturated Swabsticks and Fluid Pouches Contained in Foley/Intermittent Catheter Kits and Touchless Plus Intermittent Catheter Systems	6/27/2018	C R Bard Inc	C.R. BARD Saudi Arabia	2		0
New	Simpurity DermaPro Waterproof Silicone Tape, Safe'n'Simple, WOUNDCARE	6/26/2018	Safe N Simple, LLC	N/A	2	<a href="https://nc">https://nc</a>	
New	Space Pump IV Set, 2 Caresites, ASV, 0.2 Micron Air Eliminating Filter	6/28/2018	B. BRAUN MEDICAL INC...	Medical supplies & Services Co.Ltd Mediserv	2	<a href="https">https</a>	
New	SYNCHRO ,	6/27/2018	Stryker Neurovascular	K, MAAMOUN TAMER & COI	FSN	<a href="A/CA">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.