



SBED Weekly Update 22-May-17

Dear,

SBED team is pleased to inform you that **55** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/15/2017 to 5/21/2017
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 |
|-----------|---------------|-----------|--------------|------------|-------|------|
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Active Implantable Devices

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|--------|---|-----------|--------------|------------------------|-----|-------------------------------------|
| Update | Claria MRI™ CRT-D SureScan™ and Amplia MRI™ CRT-D SureScan™ | 5/16/2017 | Medtronic SA | Medtronic Saudi Arabia | FSN | https://nc |
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Anaesthetic and respiratory devices

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|-----|-------------------------------------|-----------|--------------------|--|-----|---------------------------|
| New | Aero Blue performance surgical gown | 5/16/2017 | Halyard Health Co. | Arabian Health Care Supply Co. (AHCSC) | FSN | https |
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| New | Arkon Anesthesia Delivery System. | 5/17/2017 | Del Mar Reynolds Medical | N/A | 2 | https |
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| New | Barrier Sets | 5/18/2017 | Molnlycke Health Care AB | h of Molnlycke Health Ca | FSN | A/Ca |
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| # New | Model V60 Ventilators ,. | 5/17/2017 | Philips Healthcare | s Healthcare Saudi Arabi | 2 | A/Ca |
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| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---|-----------|-----------------------------------|------------|-------|-------------------------------------|
| New | VORTRAN Automatic Resuscitator, VARPlus | 5/15/2017 | Vortran Medical Technology 1, Inc | N/A | 2 | https://nc |

Assistive products for persons with disability

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| New | Navitrack System OS Knee Universal, Stereotaxic instrument | 5/15/2017 | Orthosoft, Inc | N/A | 2 | https://nc |
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| New | Savaria Stairfriend | 5/15/2017 | Savaria Concord Lifts, Inc. | N/A | 2 | ttache |
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Dental devices

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| New | Hexagonal Driver Medium 1.2 | 5/16/2017 | Zimmer Biomet | Al Amin Medical Instruments Co. Ltd. | FSN | https |
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| New | Legacy P Implant | 5/21/2017 | Implant Direct LLC | N/A | FSN | A/Ca |
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Diagnostic and therapeutic radiation devices

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|-----|-----------------------------|-----------|----------------------|----------------------------|---|---------------------------|
| New | Arietta70 Ultrasound System | 5/15/2017 | Hitachi Medical Corp | ABDULREHMAN AL GOSAIBI GTB | 2 | https |
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| New | ARTIS pheno systems | 5/16/2017 | Siemens Medical Solutions | Siemens Medical Solution | FSN | A/Ca |
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| New | Assay for CA 27.29 | 5/16/2017 | Siemens Healthcare Diagnostics | ABDULREHMAN AL GOSAIBI | 2 | ttache |
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| New | Proteus One, Proteus Plus | 5/17/2017 | IBA Dosimetry GmbH | I-Faisaliah Medical System | 2 | A/Ca |
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| New | Stealth Chamber | 5/17/2017 | IBA Dosimetry GmbH | I-Faisaliah Medical System | FSN | A/Ca |
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| New | Ziehm Solo FD | 5/18/2017 | Ziehm Imaging GmbH. | Udi Health Services Co. L | 2 | A/Ca |
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Electro mechanical medical devices

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| New | Beneview T1 Patient Monitor | 5/18/2017 | Shenzhen Mindray | Salehiya Trading Est. | FSN | https |
|-----|-----------------------------|-----------|------------------|-----------------------|-----|---------------------------|

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link | |
|-----------|---------------|--|--------------|--------------------------------|--------------------------------------|------|--|
| # | New | Certegra Informatics Point-of-Care Software Used with Medrad Stellant CT Injection Systems | 5/15/2017 | Bayer Healthcare LLC.. | Scientific & Medical Equipment House | 2 | |
| | New | Corpuls3 CO2 Disposable Naso-oral Adaptor Capone | 5/17/2017 | Nihon Kohden Corporation | Arabian Medical Marketing Co. (AMCO) | 2 | https://nc |
| # | New | Inflation/Deflation Systems | 5/15/2017 | Medi-Globe GmbH | Majal Care for Trading Est. | 2 | |
| | New | Leica M525 | 5/18/2017 | Leica Microsystems Inc. | I-Faisaliah Medical System | FSN | A/Ca/ |
| # | New | NavLock Trackers Used with StealthStation Systems | 5/17/2017 | Medtronic SA | Medtronic Saudi Arabia | 2 | |
| # | New | OptiLite Multi-Use Holmium Laser Fibers | 5/15/2017 | Cook Endoscopy. | NAFA Medical | 2 | |
| | New | Patient Monitor, EtCO2 module | 5/18/2017 | EDAN Instruments, Inc. | ALHNSAH ALTBYAH Medical Services Co. | FSN | https |
| | Update | Sorin Group perfusion system – Heater-cooler 1T, Heater-cooler 3T and FlexTherm devices | 5/18/2017 | Sorin | Arabian Trade House Est. | FSN | https://nc.mdr. |
| # | New | T1 Transport Monitor/Module Battery Packs | 5/15/2017 | Shenzhen Mindray | Salehiya Trading Est. | 2 | |
| | New | Ultrasound Probe Cover (Telescopic folded with gel) | 5/17/2017 | Yafho Bio - Technology CO. Ltd | electronic technicians est | 1 | https://nc |

Hospital hardware

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|---|-----|--|-----------|--------------|-----|---|--|
| # | New | Neuromate Stereotactic Robotic Systems | 5/15/2017 | Renishaw Plc | N/A | 2 | |
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| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
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In vitro diagnostic devices

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|---|-----|--|-----------|------------------------|---|-----|--|
| # | New | ABL9 Analyzers ,. | 5/15/2017 | Radiometer America Inc | Salehiya Trading Est. | 2 | A/Ca\ |
| | New | Access Total T3, Access Thyroglobulin, Access Free T4, Access GI Monitor | 5/21/2017 | Beckman Coulter | Al-Jeel Medical & Trading Co. LTD | FSN | https://nc.mdr. |
| | New | ARCHITECT Free T4 Reagent. | 5/17/2017 | Abbott | Medical supplies & Services Co.Ltd | 2 | https |
| | New | Asserachrom Von Willebrand Factor (VWF):Collagen (CB) | 5/18/2017 | Diagnostica Stago | Medical supplies & Services Co.Ltd Mediserv | 2 | https://nc |
| | New | cobas® MPX and DPX Test, CE-IVD | 5/16/2017 | Roche Diagnostics Corp | FAROUK, MAAMOUN TAMER & COMPANY | FSN | https |
| | New | D-Dimer Test , | 5/21/2017 | DocLab GmbH | N/A | FSN | A/Ca\ |
| | New | ImmuView S. pneumoniae and L. pneumophila urinary antigen test | 5/16/2017 | SSI Diagnostica | Q.M.S. Co. Ltd | FSN | https://nc.mdr. |
| | New | Output Unit | 5/18/2017 | Roche Diagnostics Corp | MAAMOUN TAMER & C | FSN | A/Ca\ |
| | New | recomWell Campylobacter | 5/18/2017 | Mikrogen | N/A | FSN | A/Ca\ |
| | New | Synchron Systems Microalbumin (MA) Reagent | 5/17/2017 | Beckman Coulter Inc | El Seif Company | 2 | https://nc |
| | New | UniCel DxH 800/600 Cellular Analysis Systems | 5/18/2017 | Beckman Coulter | Al-Jeel Medical & Trading Co. LTD | 2 | https |

Non-active implantable devices

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|--|-----|-----------------------------|-----------|------------|-------------------------|---|-----------------------|
| | New | Affixus Hip Fracture Nail , | 5/17/2017 | Zimmer inc | im M. Al-Mana & Bros. C | 2 | A/Ca\ |
|--|-----|-----------------------------|-----------|------------|-------------------------|---|-----------------------|

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---|-----------|-------------------------|---|-------|-------------------------------------|
| New | Biomet Microfixation TraumaOne System Surgical Tray | 5/15/2017 | Biomet Microfixation | Pharma Gate Drugstore for Medicines & Medical Disposables | 2 | https://nc |
| New | Bone Dowell Harvest Tubes | 5/15/2017 | Zimmer inc | Ebrahim M. Al-Mana & Bros. Co. Ltd. | 2 | Attac |
| New | GIZA Vertebral Body Replacement | 5/15/2017 | Eden Medical | N/A | 2 | https |
| New | LOQTEQ divers | 5/18/2017 | aap Implantate AG | Saudi Import Co. Banaja | FSN | A/Ca\ |
| # New | Mitroflow LX Pericardial Prosthetic Aortic Valves | 5/15/2017 | Sorin Group. | Saudi Import Co. Banaja | 2 | 9 |
| New | SalineFilled SPECTRUM Breast Implants | 5/15/2017 | Mentor Texas Inc | Teriag International | 2 | https |
| New | Sinus-SuperFlex-635 | 5/18/2017 | Medizinische Instrument | Syts Trading Est. | FSN | A/Ca\ |
| New | Stryker PROFESS | 5/15/2017 | Stryker Instruments | I-Faisaliah Medical Syster | 2 | A/Ca\ |

Ophthalmic and optical devices

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| # Update | EZ-Load Lens Delivery System | 5/15/2017 | Valeant Pharmaceuticals International, Inc... | Medical Regulations Gate | 1 | 9 |
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Reusable devices

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|--------|--|-----------|-----------|--------------|---|--|
| Update | Pereyra Ligature Carriers, Pereyra-Raz Ligature Carriers, and Stamey Needles | 5/18/2017 | Cook Inc, | NAFA Medical | 2 | https://ncmdr. |
|--------|--|-----------|-----------|--------------|---|--|

Single-use devices

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|-------|--------------------------------|-----------|----------------|-----------------------------------|---|-----------------------|
| # New | GTube Gastronomy Feeding Tubes | 5/16/2017 | Vygon UK Ltd | Al-Jeel Medical & Trading Co. LTD | 2 | 9 |
| New | Microcatheter SONIC 1.5F | 5/17/2017 | Balt Extrusion | nar Al Jazirah Healthcare | 2 | A/Ca\ |

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---|-----------|----------------|------------------------|-------|---|
| New | Polysorb Braided Absorbable Suture and EndoStitch Loading Unit with Polysorb Suture | 5/17/2017 | Medtronic SA | Medtronic Saudi Arabia | 2 | https://ncmdr |
| Update | Polysorb Braided Absorbable Suture and EndoStitch Loading Unit with Polysorb Suture | 5/21/2017 | Medtronic SA | Medtronic Saudi Arabia | 2 | https://ncmdr |
| Update | Wingman 35 Crossing Catheter | 5/15/2017 | ReFlow Medical | N/A | FSN | https |

- * 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.