



SBED Weekly Update 23-Jan-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 1/17/2018 to 1/22/2018
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

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---------------|-----------|--------------|------------|-------|------|
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Diagnostic and therapeutic radiation devices

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|-----|---|-----------|------------------------------|-----------------------------------|---|-------------------------------------|
| New | Measurement Specialties Reusable Temperature Probe Autoclavable | 1/22/2018 | Measurement Specialties Inc. | Al-Jeel Medical & Trading Co. LTD | 2 | https://nc |
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| New | Mighty 8 Power strip, TrippLite Power strip | 1/17/2018 | Merge Healthcare Corp. | N/A | 2 | https |
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Electro mechanical medical devices

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| New | LifeVest Wearable Defibrillator | 1/17/2018 | ZOLL Medical Corp | Al Hammad Medical Services | 2 | https |
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Healthcare facility products and adaptations

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| New | Runyes Autoclave | 1/17/2018 | Runyes Medical Instrumer | Medicine Wing Est. | 2 | A/CaV |
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Hospital hardware

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|--------------------------------|-----------|--------------------|--------------------------|-------|-----------------------|
| # New | Eleganza De Luxe Hospital Beds | 1/21/2018 | Linet spol. s r.o. | Salehiya Trading Est. | 2 | Attac |
| # New | Progressa Bed Systems | 1/21/2018 | Hill Rom Inc | Medical regulations gate | 2 | Attac |

In vitro diagnostic devices

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| New | Actim RSV | 1/18/2018 | Medix Biochemica. | N/A | FSN | A/Ca |
| Update | cobas e 601, cobas e 602 MODULAR Analytics | 1/17/2018 | Roche Diagnostics Corp | FAROUK, MAAMOUN TAMER & COMPANY | FSN | https |
| New | Cyclosporine, DHEA-SO4, Folate and HbC IgM Assays | 1/21/2018 | Siemens Healthcare Diagnostics GmbH | ABDULREHMAN AL GOSAIBI GTB | FSN | https://nc |
| New | FC 500 Series Flow Cytometers | 1/21/2018 | Beckman Coulter | Al-Jeel Medical & Trading Co. LTD | 2 | https |
| New | Panther and Panther Fusion Systems with 19-in monitor | 1/22/2018 | HOLOGIC NV | Al-Jeel Medical & Trading Co. LTD | 2 | https://nc |
| New | reagent 2 in oneHbA1c FS | 1/18/2018 | ys Diagnostic Systems Gr | Ghuyum Scientific Tradir | FSN | A/Ca |
| New | Rheumatoid Factor Kit for use on SPAPLUS | 1/18/2018 | The Binding Site | FAROUK, MAAMOUN TAMER & COMPANY | FSN | https |
| Update | Vacurette Minicollect Complete 1mL Sodium Citrate 3.2%. | 1/22/2018 | Greiner Bio-One Inc | Al Hammad Medical Services | 2 | https://nc |

Non-active implantable devices

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| New | MiniMod Small Bone Plating System | 1/22/2018 | Smith & Nephew inc | Smith & Nephew inc | 2 | https |
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| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
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| New | R3 0 Hole Acetabular Shell 50mm and R3 Constrained Acetabular Liner 52mm | 1/18/2018 | Smith & Nephew inc | Smith & Nephew inc | FSN | https://nc.mdr |

Reusable devices

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| New | OSCILLATING SAW ATTACHMENT | 1/22/2018 | The Anspach Effort, Inc.. | Johnson & Johnson Medical Saudi Arabia | 2 | https |
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| New | Radiolucent Spine Surgery Frame | 1/17/2018 | Allen Medical Systems | Reem Alwasat for Trading Company. | 2 | https |
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| New | SPAG2 unit nebulizers | 1/22/2018 | Pharmaceuticals Internatio | Medical Regulations Gate | 2 | A/CA |
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| # Update | Various Trauma and Extremity Instruments , | 1/22/2018 | Zimmer inc | Ebrahim M. Al-Mana & Bros. Co. Ltd. | 2 | Attac |
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Single-use devices


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| # New | 24 G Neo-Kath Epidural and Caudal Catheter Sets | 1/21/2018 | Epimed International Inc | Pioneer Medical Company | 2 | Attac |
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| New | AFFINITY® NT Cardiotomy/Venous Reservoir (CVR) Stand-Alone , | 1/21/2018 | Medtronic SA | Medtronic Saudi Arabia | FSN | https://nc.mdr |
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| New | ETHICON VICRYL RAPIDE™ SUTURE & ENDOLOOP® COATED VICRYL® SUTURE / ENDOLOOP® PDS® II SUTURE | 1/22/2018 | Ethicon Inc. | Johnson & Johnson Medical Saudi Arabia Limited | FSN | https://nc.mdr.sfda.gov.s |
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| # New | Norm-Ject Tuberkulin Syringes | 1/22/2018 | Cook Inc, | NAFA Medical | 2 | Attac |
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| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
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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.