



SBED Weekly Update 31-Jul-18

Dear,
SBED team is pleased to inform you that **40** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 7/23/2018 to 7/29/2018
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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Anaesthetic and respiratory devices

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|-----|--|-----------|---------------|---------------|-----|---|--|
| New | arestation 620/650/650c A1, Carestation 620/650/650c A2, Carestation 30 and 9100c NXT Anesthesia Systems | 7/26/2018 | GE Healthcare | GE Healthcare | FSN | https://nc.mdr.sfda.gov.s | |
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|-----|----------------------------|-----------|-----------------|------------|-----|-----------------------|--|
| New | LEDVISION, surgical lights | 7/29/2018 | Surgiris S.A.S. | GT Medical | FSN | A/Ca\ | |
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Assistive products for persons with disability

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| New | GYM and GYM X treatment tables | 7/29/2018 | Frei AG Aktive Reha | N/A | FSN | https://nc | |
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| # | New | Steiss Activate Hoists | 7/23/2018 | Nursing Hygiene Group (N | N/A | 2 | ttache | |
|---|-----|------------------------|-----------|--------------------------|-----|---|------------------------|--|



| Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link | Affected Yes/No |
|------|--|-----------|----------------------------|----------------------|-------|-------------------------------------|-----------------|
| New | THERA-Trainer balo / THERA-Trainer verto | 7/29/2018 | Medica Medizintechnik GmbH | almadar medical Est. | FSN | https://nc | |

Complementary therapy devices

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|-----|----------------------------|-----------|------------------------------|-----|---|-------------------------------------|--|
| New | PATIENT POSITIONING SYSTEM | 7/26/2018 | Forte Automation Systems Inc | N/A | 2 | https://nc | |
|-----|----------------------------|-----------|------------------------------|-----|---|-------------------------------------|--|

Diagnostic and therapeutic radiation devices

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|-----|--|-----------|--------------------|--------------------------------------|-----|---|--|
| New | Allura Xper, integris systems. Actuator Monitor Ceiling Suspension (MCS) | 7/24/2018 | Philips Healthcare | Philips Healthcare Saudi Arabia Ltd. | FSN | https://nc.mdr.sfda | |
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| New | Artis zee and AXIOM Artis systems with Laird Cooling Unit for SSFD | 7/24/2018 | Siemens Medical Solutions | Siemens Medical Solutions | 2 | https://nc.mdr | |
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| New | Ingenuity Digital PET/CT | 7/24/2018 | Philips Healthcare | s Healthcare Saudi Arabia | 2 | A/Ca | |
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| New | MEDUCORE Standard 2 | 7/29/2018 | Weinmann. | Khateeb United Trading E | FSN | A/Ca | |
|-----|---------------------|-----------|-----------|--------------------------|-----|-------------------------|--|

Electro mechanical medical devices

| | | | | | | | |
|-------|------------------------------------|-----------|----------------|----------------|-----|---------------------------------|--|
| # New | Sonic-Fusion Flossing Toothbrushes | 7/29/2018 | Water Pik, Inc | Primeivory LLC | FSN | Attached | |
|-------|------------------------------------|-----------|----------------|----------------|-----|---------------------------------|--|

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|-----|--|-----------|--------------|------------------------|---|-------------------------------------|--|
| New | Visualase Cooled Laser Applicator System | 7/24/2018 | Medtronic SA | Medtronic Saudi Arabia | 2 | https://nc | |
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| New | Zeiss Celldiscoverer 7 | 7/24/2018 | ss - Micro Imaging Micro: | ATTIEH MEDICO LTD | 2 | A/Ca | |
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Healthcare facility products and adaptations

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| New | Access HiLow Exam Tables, Model 6501XX | 7/26/2018 | The Brewer Company, LLC | Gulf Medical Co. | 2 | https://nc | |
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In vitro diagnostic devices

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|-----|---------------------------|-----------|--------|--------------------------|-----|-------------------------|--|
| New | Alinity c Creatine Kinase | 7/24/2018 | Abbott | pplies & Services Co.Ltd | FSN | A/Ca | |
|-----|---------------------------|-----------|--------|--------------------------|-----|-------------------------|--|

| Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link | Affected Yes/No |
|----------|---|-----------|--|---|-------|---|-----------------|
| New | ARCHITECT c4000, c8000 and c16000 Processing Module | 7/24/2018 | Abbott | Medical supplies & Services Co.Ltd Mediserv | FSN | https://nc.mdr | |
| New | ARCHITECT Creatine Kinase | 7/24/2018 | Abbott | Medical supplies & Services Co.Ltd | FSN | https://nc | |
| New | ARCHITECT EBV VCA IgM Reagent Kit | 7/26/2018 | Abbott | Medical supplies & Services Co.Ltd | FSN | https://nc | |
| New | BioRad PR 4100 Microplate Reader | 7/26/2018 | Bio-Rad Laboratories Inc | Al-Jeel Medical & Trading Co. LTD | 2 | https://nc | |
| New | CFX96-IVD Optical Reaction Module | 7/23/2018 | Bio-Rad Laboratories Inc | Al-Jeel Medical & Trading Co. LTD | 2 | https://nc | |
| New | Ciprofloxacin 0.5mg/L Plate | 7/24/2018 | Mast Group Ltd. | Al Nahir Trading Co | FSN | https://nc | |
| New | Clarity Urocheck 10SG Urinalysis Strips | 7/26/2018 | Clarity Diagnostics Llc | N/A | 2 | https://nc | |
| New | Gibco Dulbecco's Modified Eagle Medium (DMEM) | 7/26/2018 | Life Technologies Limited. | Integrated Gulfbiosystems | 2 | https://nc.mdr | |
| New | IH-Com Fullversion & IH-Com for Reader | 7/23/2018 | Bio-Rad Medical Diagnostics | ABDULREHMAN AL GOSAIBI GTB | 1 | https://nc | |
| # Update | IMMULITE 1000/2000 PSA Assays | 7/24/2018 | Siemens Healthcare Diagnostics Product | AL-KAMAL Import | 2 | Attac hed | |
| # New | RAPIDLab and RAPIDPoint Blood Gas Analyzers.. | 7/29/2018 | Siemens Healthcare Diagnostics | Abdulrauf Ibrahim Batterjee & Bros. Company | 2 | Attac hed | |
| New | VITROS Chemistry Products Na+ Slides.. | 7/24/2018 | Ortho-Clinical Diagnostics | Samir Photographic Supplies Co. Ltd. | FSN | https://nc | |

| Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link | Affected Yes/No |
|------|---------------|-----------|--------------|------------|-------|------|-----------------|
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Non-active implantable devices

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|---|-----|---|-----------|----------------------|--|---|---|--|
| # | New | Affixus Hip Fracture Nails. | 7/29/2018 | Zimmer Biomet, Inc. | Isam Economic Co. | 2 | ttache | |
| | New | AperFix Femoral Implant Coring Removal Drill | 7/26/2018 | Cayenne Medical Inc. | ProMedEx | 2 | https://nc.mdr | |
| | New | OMNI Hip System, ApeXLNK Acetabular Inserts | 7/26/2018 | OMNIlife science | N/A | 2 | https://nc.mdr | |
| | New | PDS" Plus Antibacterial Suture, PDS" II (Polydioxanoe) Suture Dyed & Undyed | 7/26/2018 | Ethicon Inc. | Johnson & Johnson Medical Saudi Arabia Limited | 2 | https://nc.mdr.sfda | |

Reusable devices

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|--|--------|--|-----------|-----------------------|-------------------------------------|-----|---|--|
| | New | Hall Small Lithium Battery L3000SM | 7/29/2018 | ConMed Corporation... | Cure Development International Ltd | FSN | https://nc | |
| | Update | Invia Motion Negative Pressure Wound Therapy (NPWT) system | 7/25/2018 | Medela AG | Ebrahim M. Al-Mana & Bros. Co. Ltd. | FSN | https://nc.mdr | |

Single-use devices

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|---|-----|--|-----------|----------------------------|--------------------|-----|---|--|
| | New | «Applimed» cannula needle straight with olive, 100mm, stainless steel, G18, diameter 1.19mm, included in Medline Sterile Procedure Trays | 7/29/2018 | Medline Industries Inc... | Ikar Establishment | FSN | https://nc.mdr.sfda.gov.sa/Secure/ | |
| # | New | Arrow PICC Kits Powered by Arrow VPS Precision Stylets | 7/29/2018 | Arrow International Inc | Gulf Medical Co. | 2 | Attached | |
| | New | BLAST Bandage | 7/26/2018 | Tactical Medical Solutions | N/A | 2 | A/Ca\ | |

| Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link | Affected Yes/No |
|-------|---|-----------|--------------------------------------|-----------------------------------|-------|-------------------------------------|-----------------|
| New | Demotek Solution Administration IV Set | 7/29/2018 | Demophorius Ltd | Samir Trading and Marketing CJSC. | FSN | https://nc | |
| New | INTERCEPT Processing Set for LV Platelet Units | 7/25/2018 | Cerus Corporation | Bio Standards | FSN | https://nc | |
| # New | Portex Pulsator Arterial Blood Sampling Kits with Dry Lithium Heparin | 7/29/2018 | Smiths Medical International Limited | almadar medical Est. | 2 | Attached | |
| New | Rusch Green Lite (MAC 3) | 7/25/2018 | Teleflex Medical | m M. Al-Mana & Bros. Co | FSN | A/Ca | |

- * 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.