



**SBED Weekly Update** 30-Jan-18

Dear,  
SBED team is pleased to inform you that **26** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 1/23/2018 to 1/29/2018  
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

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---------------|-----------|--------------|------------|-------|------|
|-----------|---------------|-----------|--------------|------------|-------|------|

**Anaesthetic and respiratory devices**

|   |     |                                     |           |               |               |   |                       |
|---|-----|-------------------------------------|-----------|---------------|---------------|---|-----------------------|
| # | New | 9100c and Aelite Anesthesia Systems | 1/29/2018 | GE Healthcare | GE Healthcare | 2 | <a href="#">Attac</a> |
|---|-----|-------------------------------------|-----------|---------------|---------------|---|-----------------------|

**Dental devices**

|     |                          |           |                        |                   |   |                       |
|-----|--------------------------|-----------|------------------------|-------------------|---|-----------------------|
| New | Elements Obturation Unit | 1/29/2018 | SybronEndo Corporation | MAAMOUN TAMER & C | 2 | <a href="#">A/Ca\</a> |
|-----|--------------------------|-----------|------------------------|-------------------|---|-----------------------|

**Diagnostic and therapeutic radiation devices**

|     |   |           |                    |                                      |     |                                     |
|-----|---|-----------|--------------------|--------------------------------------|-----|-------------------------------------|
| New | Artis one systems in conjunction with Artis tables ,              | 1/23/2018 | SIEMENS            | Siemens Medical Solutions            | 2   | <a href="https://nc">https://nc</a> |
| New | Brilliance Big Bore Oncology CT, Brilliance Big Bore Radiology CT | 1/25/2018 | Philips Healthcare | Philips Healthcare Saudi Arabia Ltd. | FSN | <a href="https://nc">https://nc</a> |

| Data Type | MedicalDevice                         | Post Date | Manufacturer              | Distrbutor               | Class | Link                   |
|-----------|---------------------------------------|-----------|---------------------------|--------------------------|-------|------------------------|
| New       | IQon Spectral CT ,                    | 1/25/2018 | Philips Healthcare        | s Healthcare Saudi Arabi | FSN   | <a href="#">A/Ca\</a>  |
| New       | Metrotom 800                          | 1/29/2018 | Carl Zeiss Meditec Inc    | Gulf Medical Co.         | 2     | <a href="#">A/Ca\</a>  |
| # New     | O-Arm 1000 Surgical Imaging Systems , | 1/28/2018 | Medtronic SA              | Medtronic Saudi Arabia   | 2     | <a href="#">Attac</a>  |
| # Update  | RayStation                            | 1/28/2018 | RaySearch Laboratories AE | N/A                      | 2     | <a href="#">ttache</a> |
| New       | Syngo Imaging.                        | 1/29/2018 | Siemens Medical Solutions | Siemens Medical Solution | 2     | <a href="#">A/Ca\</a>  |
| Update    | TAYLOR SPATIAL FRAME WEBSITE SOFTWARE | 1/29/2018 | Smith & Nephew inc        | Smith & Nephew inc       | FSN   | <a href="#">https</a>  |
| New       | VeriQ and MiraQ                       | 1/25/2018 | Medistim ASA              | Gulf Medical Co.         | FSN   | <a href="#">A/Ca\</a>  |

### Electro mechanical medical devices

|       |                      |           |                            |                        |   |                        |
|-------|----------------------|-----------|----------------------------|------------------------|---|------------------------|
| # New | CRITICORE Monitors , | 1/28/2018 | rd Pcripheral Vascular (BP | C.R. BARD Saudi Arabia | 2 | <a href="#">ttache</a> |
|-------|----------------------|-----------|----------------------------|------------------------|---|------------------------|

### In vitro diagnostic devices

|          |  |           |                             |                                   |     |  |
|----------|--|-----------|-----------------------------|-----------------------------------|-----|--|
| New      | BD Phoenix Gram Negative Panels containing Colistin      | 1/25/2018 | Becton Dickinson & Co. (BD) | Becton Dickinson B.V.             | FSN | <a href="#">https://nc</a>                   |
| New      | BD Vacutainer SST II Advance Plus Blood Collection Tubes | 1/25/2018 | Becton Dickinson & Co. (BD) | Becton Dickinson B.V.             | FSN | <a href="#">https://nc</a>                   |
| New      | DIAQUICK rapid HbA1c                                     | 1/25/2018 | DIALAB GmbH                 | Abdullah A. Baghaffar             | FSN | <a href="#">A/Ca\</a>                        |
| Update   | FC 500 Series Flow Cytometers                            | 1/25/2018 | Beckman Coulter             | Al-Jeel Medical & Trading Co. LTD | 2   | <a href="#">https</a>                        |
| # Update | Panther and Panther Fusion Systems with 19-in monitor    | 1/29/2018 | HOLOGIC NV                  | Al-Jeel Medical & Trading Co. LTD | 2   | <a href="#">Attac</a><br><a href="#">hed</a> |

| Data Type | MedicalDevice   | Post Date | Manufacturer | Distrbutor                    | Class | Link                                |
|-----------|---|-----------|--------------|-------------------------------|-------|-------------------------------------|
| New       | therascreen PyroMark Gold Q24 Reagents and Pyro Buffers | 1/25/2018 | QIAGEN Ltd   | ABDULLA FOUAD HOLDING COMPANY | 2     | <a href="https://nc">https://nc</a> |

|   |     |                                 |           |         |                               |   |                        |
|---|-----|---------------------------------|-----------|---------|-------------------------------|---|------------------------|
| # | New | Xpert HIV-1 Viral Load Assays , | 1/29/2018 | Cepheid | ABDULLA FOUAD HOLDING COMPANY | 2 | <a href="#">Attach</a> |
|---|-----|---------------------------------|-----------|---------|-------------------------------|---|------------------------|

### Non-active implantable devices

|     |                 |           |                    |                    |   |                       |
|-----|-----------------|-----------|--------------------|--------------------|---|-----------------------|
| New | EVOS FLEX PLATE | 1/29/2018 | Smith & Nephew inc | Smith & Nephew inc | 2 | <a href="#">A/Cal</a> |
|-----|-----------------|-----------|--------------------|--------------------|---|-----------------------|

|     |                        |           |                    |                    |   |                       |
|-----|------------------------|-----------|--------------------|--------------------|---|-----------------------|
| New | Radial Osteotome Blade | 1/29/2018 | Smith & Nephew inc | Smith & Nephew inc | 2 | <a href="#">A/Cal</a> |
|-----|------------------------|-----------|--------------------|--------------------|---|-----------------------|

|     |                                 |           |             |     |     |                           |
|-----|---------------------------------|-----------|-------------|-----|-----|---------------------------|
| New | Salto Talaris Tibial Components | 1/23/2018 | Tornier Inc | N/A | FSN | <a href="https">https</a> |
|-----|---------------------------------|-----------|-------------|-----|-----|---------------------------|

### Single-use devices


|   |     |  |           |                   |           |   |                        |
|---|-----|--|-----------|-------------------|-----------|---|------------------------|
| # | New | DIANEAL PD4 CAPD Solution with 1.5% Dextrose and 2.5 meq/L Calcium (One Lot) | 1/29/2018 | Baxter Healthcare | Baxter AG | 2 | <a href="#">Attach</a> |
|---|-----|--|-----------|-------------------|-----------|---|------------------------|

|     |                 |           |                  |           |     |                       |
|-----|-----------------|-----------|------------------|-----------|-----|-----------------------|
| New | MARS Kit Gambro | 1/23/2018 | Gambro Lundia AB | Baxter AG | FSN | <a href="#">A/Cal</a> |
|-----|-----------------|-----------|------------------|-----------|-----|-----------------------|

|        |                 |           |                  |           |     |                       |
|--------|-----------------|-----------|------------------|-----------|-----|-----------------------|
| Update | MARS Kit Gambro | 1/29/2018 | Gambro Lundia AB | Baxter AG | FSN | <a href="#">A/Cal</a> |
|--------|-----------------|-----------|------------------|-----------|-----|-----------------------|

|     |          |           |                          |                          |   |                       |
|-----|----------|-----------|--------------------------|--------------------------|---|-----------------------|
| New | Tumark Q | 1/29/2018 | TEX Medical Technologies | nights Of Technology. Es | 2 | <a href="#">A/Cal</a> |
|-----|----------|-----------|--------------------------|--------------------------|---|-----------------------|

| Data Type | MedicalDevice | Post Date | Manufacturer | Distrbutor | Class | Link |
|-----------|---------------|-----------|--------------|------------|-------|------|
|-----------|---------------|-----------|--------------|------------|-------|------|

- \* 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.