



## SBED Weekly Update

25-Dec-17

Dear,

SBED team is pleased to inform you that **39** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 12/19/2017 to 12/24/2017  
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 |
|-----------|---------------|-----------|--------------|------------|-------|------|
|-----------|---------------|-----------|--------------|------------|-------|------|

**Active Implantable Devices**

|     |   |            |   |                                 |     |   |
|-----|---|------------|---|---------------------------------|-----|---|
| New | SynchroMed® II Implantable Drug Infusion ,  | 12/19/2017 | Medtronic SA                                      | Medtronic Saudi Arabia          | FSN | <a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a> |
| New | VALITUDE CRT-P, ALTRUA 2 Pacemaker, ESSENTIO Pacemaker, ACCOLADE Pacemaker, PROPONENT Pacemaker , VISIONIST CRT-P | 12/24/2017 | Boston Scientific Cardiac Rhythm Management Group | FAROUK, MAAMOUN TAMER & COMPANY | FSN | <a href="https://nc.mdr.sfda.gov.s">https://nc.mdr.sfda.gov.s</a> |

| Data Type | MedicalDevice   | Post Date  | Manufacturer  | Distrbutor                         | Class | Link  |
|-----------|---|------------|---|------------------------------------|-------|---|
| New       | VALITUDE CRT-P,<br>MOMENTUM CRT-D,<br>AUTOGEN CRT-D ,<br>INOGEN CRT-D,<br>VISIONIST CRT-P,<br>VIGILANT CRT-D,<br>CHARISMA CRT-D,<br>DYNAGEN CRT-D,<br>ORIGEN CRT-D,<br>RESONATE CRT-D | 12/24/2017 | Boston Scientific<br>Cardiac Rhythm<br>Management Group | FAROUK, MAAMOUN<br>TAMER & COMPANY | FSN   | <a href="https://nc.mdr.sfd.gov.sa/Secure/CA/CAView">https://nc.mdr.sfd.gov.sa/Secure/CA/CAView</a> |

### Anaesthetic and respiratory devices

|     |   |            |                                    |                               |     |   |
|-----|---|------------|------------------------------------|-------------------------------|-----|---|
| New | Equinox Advantage-<br>Nitrous Oxide/Oxygen<br>Analgesic Gas Mixing and<br>Delivery System | 12/24/2017 | O-Two Medical<br>Technologies, Inc | Dar Al Najat Medical<br>Tech. | 2   | <a href="https://nc.mdr">https://nc.mdr</a> |
| New | Fabius with Auxiliary<br>Common Gas Outlet<br>(ACGO)                                      | 12/21/2017 | Draeger Medical<br>Systems Inc     | Draeger Arabia Co. Ltd.       | FSN | <a href="https://nc">https://nc</a>         |
| New | TruVidia Wireless Receiver  | 12/21/2017 | umpf Medical Systems, In           | Medical regulations gate      | FSN | <a href="A/CAV">A/CAV</a>                   |

### Assistive products for persons with disability

|     |                         |            |                         |                         |     |                           |
|-----|-------------------------|------------|-------------------------|-------------------------|-----|---------------------------|
| New | C- Series lifts ,       | 12/24/2017 | BEKA Hospitec GmbH      | N/A                     | 2   | <a href="A/CAV">A/CAV</a> |
| New | Patterson Walking Frame | 12/24/2017 | Performance Health, inc | rmaceuticals and Medica | FSN | <a href="A/CAV">A/CAV</a> |

### Dental devices

|     |                        |            |            |                         |     |                           |
|-----|------------------------|------------|------------|-------------------------|-----|---------------------------|
| New | Tapered Screw-Vent MTX | 12/21/2017 | Zimmer inc | im M. Al-Mana & Bros. C | FSN | <a href="A/CAV">A/CAV</a> |
|-----|------------------------|------------|------------|-------------------------|-----|---------------------------|

### Diagnostic and therapeutic radiation devices

|     |   |            |                    |   |     |   |
|-----|---|------------|--------------------|---|-----|---|
| New | All Allura Xper,<br>AlluraClarity, Allura CV,<br>Allura Centron, UNIQ and<br>Integris systems , | 12/21/2017 | Philips Healthcare | Philips Healthcare<br>Saudi Arabia Ltd. | FSN | <a href="https://nc.mdr">https://nc.mdr</a> |
| New | ArcticGel Pads  | 12/21/2017 | C R Bard Inc       | C.R. BARD Saudi Arabia                  | 2   | <a href="A/CAV">A/CAV</a>                   |


| Data Type | MedicalDevice                                      | Post Date  | Manufacturer              | Distrbutor                | Class | Link                                |
|-----------|--|------------|---------------------------|---------------------------|-------|-------------------------------------|
| New       | Artis systems in conjunction with the Artis table. | 12/21/2017 | Siemens Medical Solutions | Siemens Medical Solutions | FSN   | <a href="https://nc">https://nc</a> |

|     |   |            |                    |                                      |     |   |
|-----|---|------------|--------------------|--------------------------------------|-----|---|
| New | BrightView, BrightView X, BrightView XCT, Precedence 6, Precedence 16 | 12/24/2017 | Philips Healthcare | Philips Healthcare Saudi Arabia Ltd. | FSN | <a href="https://nc.mdr">https://nc.mdr</a> |
|-----|---|------------|--------------------|--------------------------------------|-----|---|

|   |     |                          |            |         |                           |   |   |
|---|-----|--------------------------|------------|---------|---------------------------|---|---|
| # | New | syngo Dynamics Systems , | 12/20/2017 | SIEMENS | Siemens Medical Solutions | 2 | <a href="#">Attac</a>  |
|---|-----|--------------------------|------------|---------|---------------------------|---|---|

### Electro mechanical medical devices


|   |     |                   |            |           |     |   |  |
|---|-----|-------------------|------------|-----------|-----|---|--|
| # | New | LaborView Systems | 12/20/2017 | OBMedical | N/A | 2 | <a href="#">ttache</a>  |
|---|-----|-------------------|------------|-----------|-----|---|--|

|   |     |                                      |            |                    |                                   |   |   |
|---|-----|--------------------------------------|------------|--------------------|-----------------------------------|---|---|
| # | New | LIFEPAK 20e Defibrillator/Monitors , | 12/20/2017 | Physio Control Inc | Al-Jeel Medical & Trading Co. LTD | 1 | <a href="#">Attac</a>  |
|---|-----|--------------------------------------|------------|--------------------|-----------------------------------|---|---|

|     |              |            |         |     |   |                      |
|-----|--------------|------------|---------|-----|---|----------------------|
| New | Rezum System | 12/21/2017 | NXThera | N/A | 2 | <a href="#">A/Ca</a> |
|-----|--------------|------------|---------|-----|---|----------------------|

### In vitro diagnostic devices

|     |                            |            |        |                                    |     |                           |
|-----|----------------------------|------------|--------|------------------------------------|-----|---------------------------|
| New | ARCHITECT DHEA-S Reagents, | 12/19/2017 | Abbott | Medical supplies & Services Co.Ltd | FSN | <a href="https">https</a> |
|-----|----------------------------|------------|--------|------------------------------------|-----|---------------------------|

|   |     |  |            |        |   |   |   |
|---|-----|--|------------|--------|---|---|---|
| # | New | ARCHITECT Total Prostate Specific Antigen Reagents , | 12/20/2017 | Abbott | Medical supplies & Services Co.Ltd Mediserv | 2 | <a href="#">Attac</a>  |
|---|-----|--|------------|--------|---|---|---|

|     |                       |            |        |                                    |     |                      |
|-----|-----------------------|------------|--------|------------------------------------|-----|----------------------|
| New | CELL-DYN Emerald 22 , | 12/19/2017 | Abbott | Medical supplies & Services Co.Ltd | FSN | <a href="#">A/Ca</a> |
|-----|-----------------------|------------|--------|------------------------------------|-----|----------------------|

|     |                    |            |                        |                   |     |                      |
|-----|--------------------|------------|------------------------|-------------------|-----|----------------------|
| New | Elecsys BRAHMS PCT | 12/24/2017 | Roche Diagnostics Corp | MAAMOUN TAMER & C | FSN | <a href="#">A/Ca</a> |
|-----|--------------------|------------|------------------------|-------------------|-----|----------------------|

|     |   |            |  |                 |   |   |
|-----|---|------------|--|-----------------|---|---|
| New | IMMULITE/IMMULITE 1000 IMMULITE 2000/IMMULITE 2000 XPi Assays , | 12/24/2017 | Siemens Healthcare Diagnostics Product | AL-KAMAL Import | 2 | <a href="https://nc.mdr">https://nc.mdr</a> |
|-----|---|------------|--|-----------------|---|---|

| Data Type | MedicalDevice  | Post Date  | Manufacturer                | Distrbutor                 | Class | Link  |
|-----------|--|------------|-----------------------------|----------------------------|-------|---|
| New       | SPOTCHEM II Glucose, SPOTCHEM II PANEL-1, SPOTCHEM II PANEL-V and SPOTCHEM II PANEL-V2 | 12/24/2017 | ARKRAY GLOBAL business, Inc | Enmaeyat Trading Co.       | FSN   | <a href="https://nc.mdr.sfda">https://nc.mdr.sfda</a> |
| New       | Vacurette Minicollect Complete 1mL Sodium Citrate 3.2%.                                | 12/24/2017 | Greiner Bio-One Inc         | Al Hammad Medical Services | 2     | <a href="https://nc">https://nc</a>                   |

### Non-active implantable devices

|     |  |            |                         |  |     |   |
|-----|--|------------|-------------------------|--|-----|---|
| New | GLOBAL UNITE Platform Shoulder System  | 12/21/2017 | DePuy Ireland UC        | Johnson & Johnson Medical Saudi Arabia | FSN | <a href="https">https</a>   |
| New | KYPHON Express Directional Bone Filler.  | 12/21/2017 | Medtronic Sofamor Danek | Al Amin Medical Instruments Co. Ltd.   | FSN | <a href="https">https</a>   |
| New | NDm-40-10 Zirkolith Implant with NDm-P14 Pin   | 12/21/2017 | Z-Systems AG            | N/A                                    | FSN | <a href="https://nc">https://nc</a>                                       |
| New | Persona Partial Knee Spacer Blocks Size 8mm, 9mm, 10mm, 12mm, 14mm   | 12/21/2017 | Zimmer, INC....         | Medical Regulations Gate               | FSN | <a href="https://nc.mdr">https://nc.mdr</a>                               |
| New | REVITAN MODULAR RASP DISTAL CURVED   | 12/24/2017 | Zimmer, INC....         | Medical Regulations Gate               | FSN | <a href="https">https</a>   |
| New | uncoated knee and hip prostheses, coated knee femur prosthesis, patellofemoral joint prosthesis, femoral head bipolar component, press fit femoral stem prosthesis | 12/24/2017 | Zimmer, INC....         | Medical Regulations Gate               | FSN | <a href="https://nc.mdr.sfda.gov.sa/Se">https://nc.mdr.sfda.gov.sa/Se</a> |
| New | Uphold LITE with Capio SLIM and Solyx Single Incision Sling System ,   | 12/24/2017 | Boston Scientific       | Gulf Medical Co.                       | 1   | <a href="https://nc">https://nc</a>                                       |

### Reusable devices

| Data Type | MedicalDevice  | Post Date  | Manufacturer         | Distrbutor                   | Class | Link                          |
|-----------|--|------------|----------------------|------------------------------|-------|-------------------------------|
| # New     | Slap Hammers and Impactors Contained in Various Orthopedic Instrument Sets | 12/20/2017 | Stryker Orthopaedics | Zimmo Trading Establishment. | 2     | <a href="#">Attac<br/>hed</a> |



|     |                            |            |                                      |     |     |                           |
|-----|----------------------------|------------|--------------------------------------|-----|-----|---------------------------|
| New | Steam Sterilizer ProtoCERT | 12/21/2017 | F. & M. Lautenschläger GmbH & Co. KG | N/A | FSN | <a href="https">https</a> |
|-----|----------------------------|------------|--------------------------------------|-----|-----|---------------------------|

### Single-use devices

|       |   |            |                |                       |   |                               |
|-------|---|------------|----------------|-----------------------|---|-------------------------------|
| # New | Alaris Extension Sets with Microbore Tubing , | 12/20/2017 | BD Biosciences | Becton Dickinson B.V. | 2 | <a href="#">Attac<br/>hed</a> |
|-------|---|------------|----------------|-----------------------|---|-------------------------------|



|       |  |            |                           |                    |   |                               |
|-------|--|------------|---------------------------|--------------------|---|-------------------------------|
| # New | Custom Kits Containing Ecolab Disposable Light Handle Covers | 12/20/2017 | Medline Industries Inc... | Ikar Establishment | 2 | <a href="#">Attac<br/>hed</a> |
|-------|--|------------|---------------------------|--------------------|---|-------------------------------|



|     |                                     |            |              |                        |   |                           |
|-----|-------------------------------------|------------|--------------|------------------------|---|---------------------------|
| New | I125 CE Marked QuickLink Cartridges | 12/21/2017 | C R Bard Inc | C.R. BARD Saudi Arabia | 2 | <a href="https">https</a> |
|-----|-------------------------------------|------------|--------------|------------------------|---|---------------------------|

|     |                         |            |                   |                  |   |                       |
|-----|-------------------------|------------|-------------------|------------------|---|-----------------------|
| New | Nv Guider Catheter 90cm | 12/24/2017 | Boston Scientific | Gulf Medical Co. | 2 | <a href="#">A/CaV</a> |
|-----|-------------------------|------------|-------------------|------------------|---|-----------------------|

|     |                      |            |           |              |   |                       |
|-----|----------------------|------------|-----------|--------------|---|-----------------------|
| New | Transseptal Needle , | 12/24/2017 | Cook Inc, | NAFA Medical | 1 | <a href="#">A/CaV</a> |
|-----|----------------------|------------|-----------|--------------|---|-----------------------|

|       |                            |            |                            |     |   |                        |
|-------|----------------------------|------------|----------------------------|-----|---|------------------------|
| # New | Voice Prosthesis Brushes , | 12/20/2017 | isight Medical Products Lt | N/A | 2 | <a href="#">ttache</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.