



**SBED Weekly Update** 19-Dec-17

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 12/11/2017 to 12/18/2017  
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 |
|-----------|---------------|-----------|--------------|------------|-------|------|
|-----------|---------------|-----------|--------------|------------|-------|------|

**Anaesthetic and respiratory devices**

|     |                             |            |               |               |     |                       |
|-----|-----------------------------|------------|---------------|---------------|-----|-----------------------|
| New | CARESCAPE R860 ventilator , | 12/14/2017 | GE Healthcare | GE Healthcare | FSN | <a href="#">https</a> |
|-----|-----------------------------|------------|---------------|---------------|-----|-----------------------|

|     |                      |            |               |               |     |                       |
|-----|----------------------|------------|---------------|---------------|-----|-----------------------|
| New | Lullaby Resus plus , | 12/12/2017 | GE Healthcare | GE Healthcare | FSN | <a href="#">A/CaV</a> |
|-----|----------------------|------------|---------------|---------------|-----|-----------------------|

**Assistive products for persons with disability**

|     |                  |            |                           |     |   |                       |
|-----|------------------|------------|---------------------------|-----|---|-----------------------|
| New | C-Series Lifts , | 12/14/2017 | Waverley Glen Systems Ltc | N/A | 2 | <a href="#">A/CaV</a> |
|-----|------------------|------------|---------------------------|-----|---|-----------------------|

|     |                         |            |                         |     |   |                       |
|-----|-------------------------|------------|-------------------------|-----|---|-----------------------|
| New | Hercules Patient Lifter | 12/14/2017 | Healthcare Equipment Pl | N/A | 2 | <a href="#">A/CaV</a> |
|-----|-------------------------|------------|-------------------------|-----|---|-----------------------|

**Diagnostic and therapeutic radiation devices**

|     |   |            |                          |                                 |   |                            |
|-----|---|------------|--------------------------|---------------------------------|---|----------------------------|
| New | FDR Visionary Suite with CH200 stationary xray system | 12/13/2017 | FUJIFILM Medical Systems | FAROUK, MAAMOUN TAMER & COMPANY | 2 | <a href="#">https://nc</a> |
|-----|---|------------|--------------------------|---------------------------------|---|----------------------------|

| Data Type | MedicalDevice             | Post Date  | Manufacturer | Distrbutor | Class | Link                  |
|-----------|---------------------------|------------|--------------|------------|-------|-----------------------|
| New       | Telemis-Medical Software. | 12/18/2017 | Telemis S.A. | N/A        | FSN   | <a href="#">A/Cal</a> |

### Electro mechanical medical devices

|       |  |            |                   |                                 |   |                                     |
|-------|--|------------|-------------------|---------------------------------|---|-------------------------------------|
| New   | BioStable 5F DL55CM MST70 KIT NonValved w/ Nit GW        | 12/18/2017 | AngioDynamics Inc | FAROUK, MAAMOUN TAMER & COMPANY | 2 | <a href="https://nc">https://nc</a> |
| # New | ONDAL AC2000 Spring Arms Used with X'TEN Surgical Lights | 12/11/2017 | MAQUET Inc        | Gulf Medical Co.                | 2 | <a href="#">Attac hed</a>           |

### In vitro diagnostic devices

|        |   |            |  |                                      |     |                                     |
|--------|---|------------|--|--------------------------------------|-----|-------------------------------------|
| Update | ARCHITECT c4000 Cuvette Segment                   | 12/12/2017 | Abbott Laboratories Inc                    | Medical supplies & Services Co.Ltd   | FSN | <a href="https">https</a>           |
| New    | enGen Laboratory Automation System.               | 12/18/2017 | Ortho-Clinical Diagnostics                 | Samir Photographic Supplies Co. Ltd. | 2   | <a href="https">https</a>           |
| New    | MIA FORA NGS HLA FLEX 11 KIT (24 tests).          | 12/14/2017 | BioArray Solutions Ltd                     | N/A                                  | 2   | <a href="https">https</a>           |
| New    | Monoclonal Mouse Anti-Human CDX2, Clone DAK-CDX2. | 12/14/2017 | Dako North America Inc                     | Dar Al-Zahrawi Medical Co. LLC       | 2   | <a href="https://nc">https://nc</a> |
| # New  | Rapid fFN Cassette Kits for TLIQ Tests            | 12/11/2017 | Hologic Inc.                               | ABDULLA FOUAD HOLDING COMPANY        | 2   | <a href="#">Attac</a>               |
| New    | Thermo Scientific Oxoid Brilliance Staph 24 Agar  | 12/18/2017 | ThermoFisher Scientific Microbiology Perth | Fuad Abdul Jalil Al Fadhli & Sons    | FSN | <a href="https">https</a>           |

### Non-active implantable devices

|     |   |            |                    |     |   |   |
|-----|---|------------|--------------------|-----|---|---|
| New | MCK Tibial Baseplate-RM/LL-SZ 2 and MCK Tibial Baseplate-RM/LL-SZ 7 | 12/14/2017 | MAKO Surgical Corp | N/A | 2 | <a href="https://nc.mdr">https://nc.mdr</a> |
| New | Omni Spine Anterior Cervical Plate System                           | 12/14/2017 | Amendia, Inc       | N/A | 2 | <a href="https">https</a>                   |

| Data Type | MedicalDevice                        | Post Date  | Manufacturer   | Distrbutor               | Class | Link                                |
|-----------|--------------------------------------|------------|----------------|--------------------------|-------|-------------------------------------|
| New       | OPTIPAC 40 and 80 REFOBACIN REVISION | 12/18/2017 | Zimmer, INC... | Medical Regulations Gate | FSN   | <a href="https://nc">https://nc</a> |

|     |  |            |                     |          |   |                                     |
|-----|--|------------|---------------------|----------|---|-------------------------------------|
| New | PopLok Knotless Suture Anchor with Disposable Driver | 12/18/2017 | ConMed Corporation. | ProMedEx | 2 | <a href="https://nc">https://nc</a> |
|-----|--|------------|---------------------|----------|---|-------------------------------------|

### Reusable devices

|     |                                  |            |                                  |  |     |                                     |
|-----|----------------------------------|------------|----------------------------------|--|-----|-------------------------------------|
| New | Hemotherm Models 400CE and 400MR | 12/18/2017 | Cincinnati Sub-Zero Products Inc | Al Shoumoukh Trading for Technical and | FSN | <a href="https://nc">https://nc</a> |
|-----|----------------------------------|------------|----------------------------------|--|-----|-------------------------------------|

|   |     |                                       |            |                         |                       |   |                                   |
|---|-----|---------------------------------------|------------|-------------------------|-----------------------|---|-----------------------------------|
| # | New | PASS OCT Occipital Screwdriver Shafts | 12/11/2017 | Medicrea International. | Salehiya Trading Est. | 2 | <a href="https://nc">Attached</a> |
|---|-----|---------------------------------------|------------|-------------------------|-----------------------|---|-----------------------------------|

### Single-use devices


|     |   |            |                                |                        |   |                                     |
|-----|---|------------|--------------------------------|------------------------|---|-------------------------------------|
| New | Balloon wall thickness of ATLAS® GOLD PTA Dilatation Catheter | 12/12/2017 | Bard Pcripheral Vascular (BPV) | C.R. BARD Saudi Arabia | 2 | <a href="https://nc">https://nc</a> |
|-----|---|------------|--------------------------------|------------------------|---|-------------------------------------|

|   |     |   |            |               |     |   |                                   |
|---|-----|---|------------|---------------|-----|---|-----------------------------------|
| # | New | E.M. Adams Trays and Kits Containing Medline Aplicare Povidone Iodine Prep Pads | 12/12/2017 | Moore Medical | N/A | 2 | <a href="https://nc">Attached</a> |
|---|-----|---|------------|---------------|-----|---|-----------------------------------|

|     |   |            |                   |                  |   |   |
|-----|---|------------|-------------------|------------------|---|---|
| New | Malecot Nephrostomy Catheter System, Malecot Nephrostomy Catheter Set, Re-Entry™ Malecot Nephrostomy Catheter Set and Percutaneous Access Set | 12/14/2017 | Boston Scientific | Gulf Medical Co. | 1 | <a href="https://nc.mdr.sFDA.gov.sa/Se">https://nc.mdr.sFDA.gov.sa/Se</a> |
|-----|---|------------|-------------------|------------------|---|---|

|     |                    |            |              |                        |     |                                |
|-----|--------------------|------------|--------------|------------------------|-----|--------------------------------|
| New | NIM Eclipse System | 12/18/2017 | Medtronic SA | Medtronic Saudi Arabia | FSN | <a href="https://nc">A/Ca\</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.