

Dear,  
NCMDR team send a weekly update every week containing the latest Field Safety Corrective Action/Recalls of medical devices/products on SFDA website.

عزيزي،  
يقوم المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بإرسال تقرير اسبوعي عن آخر اشعارات إنذارات السلامة / الاستدعاءات للأجهزة والمستلزمات الطبية المنشورة على موقع الهيئة العامة للغذاء والدواء

\* Role of NCMDR officer:

\* مسؤولية ضابط الاتصال:

- Disseminate and share the information with other Departments within healthcare facility and Ensuring that the healthcare facility is free of any affected device/product.
- Communicate with NCMDR Team and Authorized Representative of the manufacturer if there is any affected device/product.

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.
- التواصل مع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ومع الممثل القانوني للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.

Hospital name:  
Date:  
Hospital affected by any medical device/product in this report: No Yes

اسم المستشفى:  
التاريخ:  
يوجد أجهزة متأثرة بالمستشفى ضمن القائمة: لا نعم

• The yellow highlights Indicates that medical devices subject to removal and/ or destroyed action.

• الإشعارات المظللة بالأصفر تشير الى سحب او إتلاف جهاز طبي.

• NCMDR Team Recommend ensuring the listed Authorized representative/Distributor in this report as they may differ from the Authorized representative/Distributor you are dealing with

• الممثلين القانونيين/الموزعين في هذا التقرير قد يختلفون عن الممثلين القانونيين/الموزعين الذين تتعاملون معهم.

• The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI.

• هذه العلامة (#) في الجهة اليسرى من التقرير تشير إلى ان اشعار انذار السلامة من منظمة (ECRI).


• Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

• لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.

NCMDR Weekly Update

13-Feb-19

Dear,  
 NCMDR team is pleased to inform you that **52** new FSQA/recalls for medical devices and products posted on SFDA website for the period of **04-Feb-19** to **10-Feb-19** In order to view more details, click the links or attachments 

عزيزي،  
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **52** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **04-Feb-19** الى **10-Feb-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط او المرفقات 

| MedicalDevice | Manufacturer | Authorized Representative /Distributor | Link | Affected Yes/No |
|---------------|--------------|--|------|-----------------|
|---------------|--------------|--|------|-----------------|

### Active Implantable Devices

|                                |              |                        |   |  |
|--------------------------------|--------------|------------------------|---|--|
| Adapta Dual Chamber Pacemakers | Medtronic SA | Medtronic Saudi Arabia | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec</a> |  |
|--------------------------------|--------------|------------------------|---|--|

|             |                         |     |   |  |
|-------------|-------------------------|-----|---|--|
| Fitbone TAA | Wittenstein intens GmbH | N/A | <a href="/Secure/CA/CAViewRecal">/Secure/CA/CAViewRecal</a> |  |
|-------------|-------------------------|-----|---|--|

### Anaesthetic and respiratory devices

|   |               |               |   |  |
|---|---------------|---------------|---|--|
| CARESCAPE R860 Inspiratory Safety Guard | GE Healthcare | GE Healthcare | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRec</a> |  |
|---|---------------|---------------|---|--|

|  |               |               |   |  |
|--|---------------|---------------|---|--|
| Centricity High Acuity Anesthesia, Centricity High Acuity Critical Care Systems with versions 4.5, 5.0 and 5.1 - Drug Infusion Volumes | GE Healthcare | GE Healthcare | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=13847">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=13847</a> |  |
|--|---------------|---------------|---|--|

|   | MedicalDevice                       | Manufacturer       | Authorized Representative /Distributor | Link | Affected Yes/No   |
|---|-------------------------------------|--------------------|--|------|---|
| # | Ultipor 25 Breathing System Filters | Pall Life Sciences | Arabian Trade House Est.               |      |  |


### Dental devices


|  |                           |                          |                 |   |  |
|--|---------------------------|--------------------------|-----------------|---|--|
|  | UltraTemp & UltraTemp REZ | Ultradent Products, Inc. | DENTAL ERA EST. | <a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a> |  |
|--|---------------------------|--------------------------|-----------------|---|--|

### Diagnostic and therapeutic radiation devices

|  |                                   |                        |  |   |  |
|--|-----------------------------------|------------------------|--|---|--|
|  | ARIA Radiation Therapy Management | Varian Medical Systems | Varian Medical Systems Arabia Commercial Limited | <a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1</a> |  |
|--|-----------------------------------|------------------------|--|---|--|

|   |                               |              |                     |   |  |
|---|-------------------------------|--------------|---------------------|---|--|
| # | COBRA Fusion Ablation Systems | AtriCure Inc | Saudi Sicli Company |  |  |
|---|-------------------------------|--------------|---------------------|---|--|

|   |                                |             |     |   |  |
|---|--------------------------------|-------------|-----|---|--|
| # | Cobra Two-Channel EMG ET Tubes | Neurovision | N/A |  |  |
|---|--------------------------------|-------------|-----|---|--|




|   |  |        |   |   |  |
|---|--|--------|---|---|--|
| # | FreeStyle Libre Flash Glucose Monitoring Systems | Abbott | Medical supplies & Services Co.Ltd Mediserv |  |  |
|---|--|--------|---|---|--|

|  |                |                    |                                |   |  |
|--|----------------|--------------------|--------------------------------|---|--|
|  | Sonolith i-sys | DAP TMS FRANCE SAS | Dar Al-Zahrawi Medical Co. LLC | <a href="/Secure/CA/CaViewRecal">/Secure/CA/CaViewRecal</a> |  |
|--|----------------|--------------------|--------------------------------|---|--|

|  |                             |                        |  |   |  |
|--|-----------------------------|------------------------|--|---|--|
|  | VariSource HDR and GammaMed | Varian Medical Systems | Varian Medical Systems Arabia Commercial Limited | <a href="https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.s/Secure/CA/CaViewRec</a> |  |
|--|-----------------------------|------------------------|--|---|--|

### Electro mechanical medical devices



| MedicalDevice  | Manufacturer             | Authorized Representative /Distributor | Link  | Affected Yes/No |
|--|--------------------------|--|---|-----------------|
| Arrow CVC, Arrow® Two-Lumen Central Venous Catheterization Kit with Blue FlexTip® Catheter | Arrow International Inc  | Gulf Medical Co.                       | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13834">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&amp;rid=13834</a> |                 |
| # Fetal Spiral Electrodes  | Philips Healthcare       | Philips Healthcare Saudi Arabia Ltd.   |    |                 |
| Hemodynamic Application R1.0.1   | Philips Healthcare       | Philips Healthcare Saudi Arabia Ltd.   | <a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>   |                 |
| # iBed Wireless-Enabled InTouch ICU Beds, S3 MedSurg Beds, and Secure II MedSurg Beds      | Stryker Medical          | Al-Jeel Medical & Trading Co. LTD      |    |                 |
| # LIFEPAK 15 Defibrillators/Monitors   | Stryker                  | Al-Jeel Medical & Trading Co. LTD      |    |                 |
| # Model 92810 Smart Disclosure Systems   | Spacelabs Healthcare Inc | Gulf Medical Co.                       |    |                 |
| # Model 96280 Xhibit Telemetry Receivers   | Spacelabs Healthcare Inc | Gulf Medical Co.                       |    |                 |
| # OER-Pro Automated Endoscope Reprocessors   | Olympus                  | Salehiya Trading Est.                  |    |                 |


|   | MedicalDevice                 | Manufacturer                | Authorized Representative /Distributer | Link  | Affected Yes/No |
|---|-------------------------------|-----------------------------|--|---|-----------------|
| # | Various FACSria Systems       | Becton Dickinson & Co. (BD) | Becton Dickinson B.V.                  |  |                 |
| # | Vial2Bag Fluid Transfer Sets  | Cardinal-Health             | MEDICARE DRUG STORE COMPANY            |  |                 |
| # | Vial2Bag Fluid Transfer Sets. | Medline Industries, Inc.    | Cure Development International Ltd     |  |                 |

### Healthcare facility products and adaptations

|  |              |                         |           |  |  |
|--|--------------|-------------------------|-----------|--|--|
|  | Basin liners | terisets Medical Produc | Baxter AG | <a href="#">/Secure/CA/CaViewRecal</a> |  |
|--|--------------|-------------------------|-----------|--|--|



### In vitro diagnostic devices

|   |  |                        |   |   |  |
|---|--|------------------------|---|---|--|
| # | AIA360 Analyzer  | Tosoh Corporation      | DULLA FOUAD HOLDING COMPA                   |    |  |
|   | ARCHITECT Estradiol Reagent Kit, Alinity i Estradiol Reagent Kit | Abbott                 | Medical supplies & Services Co.Ltd Mediserv | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13846">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=13846</a> |  |
|   | CoaguChek XS Test Strips INST 48CT                               | Roche Diagnostics Corp | FAROUK, MAAMOUN TAMER & COMPANY             | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>   |  |
| # | cobas Liat Systems   | Roche Diagnostics Corp | DUK, MAAMOUN TAMER & COMP                   |    |  |
|   | Elecsys Anti HAV IgM   | Roche Diagnostics Corp | FAROUK, MAAMOUN TAMER & COMPANY             | <a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>   |  |

| MedicalDevice                             | Manufacturer               | Authorized Representative /Distributor            | Link  | Affected Yes/No |
|---|----------------------------|---|---|-----------------|
| # Eurotrol HemoTrol Hemoglobin Controls.. | Eurotrol B.V               | Raez Environmental System & Advanced Technologies |                        |                 |
| FC 500 Series Flow Cytometers ,           | Beckman Coulter            | Al-Jeel Medical & Trading Co. LTD                 | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |                 |
| STA – VWF:RCO reagent .                   | Diagnostica Stago          | Medical supplies & Services Co.Ltd Mediserv       | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |                 |
| VITROS MicroWell Assays, Folate, Free PSA | Ortho-Clinical Diagnostics | Samir Photographic Supplies Co. Ltd.              | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |                 |
| Xpert GBS.                                | Cepheid                    | DULLA FOUAD HOLDING COMPA                         | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">/Secure/CA/CaViewRecal</a>                        |                 |

### Non-active implantable devices

|   |                       |                                       |   |  |
|---|-----------------------|---------------------------------------|---|--|
| Agile Biliary RX Fully Covered Stent System | Boston Scientific     | Gulf Medical Co.                      | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |
| Calix Lumbar Spinal Implant System          | XTANT MEDICAL INC     | N/A                                   | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |
| # Commander Delivery Systems.               | Edwards Lifesciences  | Arabian Health Care Supply Co. (AHSC) |                      |  |
| Commander Delivery Systems.                 | Edwards Lifesciences  | Arabian Health Care Supply Co. (AHSC) | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |
| HydroPearl microspheres                     | Terumo Medical Corp.. | Al-Jeel Medical & Trading Co. LTD     | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |




| MedicalDevice  | Manufacturer                           | Authorized Representative /Distributer | Link  | Affected Yes/No |
|--|--|--|---|-----------------|
| Instrument Tray, Basic T2 Femur Long                             | Stryker Trauma AG                      | Al-Faisaliah Medical System            | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>   |                 |
| # Nellix, Endovascular Aneurysm Sealing System..                 | Endologix international holding B.V.   | Tart Medical                           |    |                 |
| # Trabecular Metal Tibial Half Block Augments                    | Zimmer, INC....                        | Medical Regulations Gate               |    |                 |
| Verso Shoulder Humeral Shells and Verso Shoulder Stemmed Humeral | Innovative Design Orthopaedics Limited | N/A                                    | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13840">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=13840</a> |                 |

### Reusable devices

|                                   |                          |   |   |  |
|-----------------------------------|--------------------------|---|---|--|
| Perifix Catheter Connector.       | B. BRAUN MEDICAL INC...  | Medical supplies & Services Co.Ltd Mediserv | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |
| Sonosite L25 Needle Guide Bracket | FUJIFILM SonoSite, Inc . | Techno-Orbits Establishment                 | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a> |  |

### Single-use devices

|   |                           |                  |   |  |
|---|---------------------------|------------------|---|--|
| 5x75mm Kii Fios Advanced Fixation Access System , | Applied Medical Resources | Dawha Medical    | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=1</a> |  |
| AXIUS Blower Mister                               | Getinge Disinfection AB   | Gulf Medical Co. | <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>   |  |

|   | MedicalDevice                          | Manufacturer      | Authorized Representative /Distributor | Link  | Affected Yes/No |
|---|--|-------------------|--|---|-----------------|
| # | ChemoLock Vial Spikes                  | ICU Medical, Inc  | AL-KAMAL Import                        |  |                 |
|   | DENTASEPT SH PRO WIPES                 | D.M.D             | N/A                                    | <a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>                     |                 |
| # | Transseptal Needles                    | Cook Inc,         | Majal Care for Trading Est.            |  |                 |
|   | UNISEPTA FOAM 2 WIPES                  | USF Healthcare SA | Medical Vision Est.                    | <a href="https://ncmdr.sfda.gov.s">https://ncmdr.sfda.gov.s</a>                     |                 |
| # | Wire Guides Contained in Various Trays | Cook Inc,         | Majal Care for Trading Est.            |  |                 |