

Kingdom of Saudi Arabia Saudi Food & Drug Authority



المملكة العربية السعودية الهيئة العامة للغذاء والدواء

Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

FSCA Weekly Update

07-Feb-21

Attached below is the weekly report of Field Safety Corrective Actions (FSCAs) for the period:

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية لإذارات السلامة للفترة:

From 31-Jan-21 من
To 07-Feb-21 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

و المتأثرة بها المملكة والتي جاري متابعتها مع الممثلين المعتمدين لإتمام تنفيذ الإجراءات التصحيحية.

* Role of contact officer:

* مسؤولية ضابط الاتصال:

*** Kindly respond to the weekly report in both cases either you are affected or not affected.**

*** نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر.**

- 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 the Authorised Representative of the manufacturer if there is any device/product affected by a FSCA

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من الإجراءات التصحيحية للسلامة الميدانية.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من الإجراءات التصحيحية لإذارات السلامة.

Hospital name:

اسم المستشفى:

Date:

التاريخ:

Hospital affected by any device/product in this report:

يوجد أجهزة/منتجات متأثرة بالمستشفى ضمن القائمة:

Yes

نعم

No

لا

- The yellow highlights indicates that medical devices subject to removal action.
- To identify the affected serial numbers/lots, please open the link.

- الإجراءات المظللة بالأصفر تشير إلى إجراء سحب الجهاز الطبي.
- لمعرفة الطراز أو الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Field Safety Corrective Actions (FSCA):

14

عدد الإجراءات التصحيحية لإنذارات السلامة

| Medical Device | Manufacturer | Authorized Representative /Distributor | Link | Affected Yes/No |
|----------------|--------------|--|------|-----------------|
|----------------|--------------|--|------|-----------------|

Active Implantable Devices

| | | | | |
|--|--------------|------------------------|---|--|
| Subset of Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) | Medtronic SA | Medtronic Saudi Arabia | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=155 | |
|--|--------------|------------------------|---|--|

Diagnostic and therapeutic radiation devices

| | | | | |
|---|---------------------------|---------------------------|---|--|
| ACUSON Sequoia ultrasound systems , | SIEMENS | Siemens Medical Solutions | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| Alphenix and Infinix Interventional X-Ray System Catheterization Tables | Canon Inc | Gulf Medical Co. | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| Alphenix and Infinix Interventional X-Ray System Catheterization Tables | Canon Inc | Gulf Medical Co. | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| Interventional X-Ray Systems | Canon Inc | Gulf Medical Co. | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| Interventional X-Ray Systems | Canon Inc | Gulf Medical Co. | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| syngo.via all systems with software version VB40A or VB40B | Siemens Medical Solutions | Siemens Medical Solutions | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |

Electro mechanical medical devices

| | | | | |
|---|---------------------------|-----------------------------------|---|--|
| Datascope CARDIOSAVE Intra-Aortic Balloon Pumps | MAQUET Cardiovascular LLC | Al-Jeel Medical & Trading Co. LTD | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
| Prismaflex Control Unit ,. | Baxter Healthcare | Baxter AG | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |

In vitro diagnostic devices

| Medical Device | Manufacturer | Authorized Representative /Distributor | Link | Affected Yes/No |
|---|------------------------------------|--|---|-----------------|
| Atellica IM and ADVIA Centaur XP/XPT Free Prostate-Specific Antigen (fPSA) | Siemens Healthcare Diagnostics Inc | ABDULREHMAN AL GOSAIBI GTB | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp | |
| BioFire® FilmArray® Blood Culture Identification (BCID) Panel and BioFire® Blood Culture Identification 2 (BCID2) Panel | bioMerieux Inc | Al-Jeel Medical & Trading Co. LTD | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=155 | |
| VIDAS CVM IgM. | bioMerieux Inc | Jeel Medical & Trading Co. L | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=155 | |

Medical software

| | | | | |
|----------|------------|---------------|---|--|
| FetaLink | CERNER COR | Bio Standards | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=155 | |
|----------|------------|---------------|---|--|

Single-use devices

| | | | | |
|---|-----------------------------|------------|---|--|
| ELISIO 17-H, ELISIO 19-H, and ELISIO 19-M | Nipro Medical Corporation.. | Spectromed | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=155 | |
|---|-----------------------------|------------|---|--|