

Safety Alerts Weekly Update

Report Reference: WU2615
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التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

below is the weekly report of Safety Alerts for the period:

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 29-Mar-26 من
To 04-Apr-26 إلى

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

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

* Kindly respond to the weekly report in both cases either you are affected or not affected though the following link:

* نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر وذلك من خلال الرابط أدناه:

<https://surveys.sfda.gov.sa/surveys/?s=7KN979YXNHPPRENX>



* Role of contact officer:

* مسؤولية ضابط الاتصال:

- Disseminate and share the information with other departments within the healthcare facility and ensure 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 Safety Alert
- To identify the affected serial numbers/lots, please open the Safety link.

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إبذار السلامة:

No. of Safety Alerts: 16 عدد إنذارات السلامة

| Safety Alert No. | NCMDR Ref. | Medical Device | Manufacturer | Authorized Representative /Importer | Link | Medical Device Category |
|------------------|------------------|--|---|--------------------------------------|--|------------------------------------|
| 1 | SA-29-03-26-1295 | Radius VSM ECG Electrodes and Pressure Cuffs | Masimo Corporation | Masimo International SARL | https://ade.sfda.go | Electro mechanical medical devices |
| 2 | SA-01-04-26-1338 | Atellica CH Analyzer Atellica CI Analyzer | Siemens Healthcare Diagnostics GmbH | ABDULREHMAN AL GOSAIBI GTB | https://ade.sfda.go | In vitro diagnostic devices |
| 3 | SA-27-03-26-1292 | Multi-parameter Command Module | Spacelabs Healthcare Inc | Gulf Medical Co. | https://ade.sfda.go | Electro mechanical medical devices |
| 4 | SA-26-03-26-1291 | M ZN-AIR BATTERY PAK | Advanced Bionics Corp. | Gulf Medical Co. | https://ade.sfda.go v.sa/Fsca/PublishD | Electro mechanical medical devices |
| 5 | SA-29-03-26-1299 | corpuls3 Product-family with Glasgow Full Scale or HES-License | GS Elektromedizinische Geräte G. Stemple GmbH | Al Khateeb United Trading Est. | https://ade.sfda.go v.sa/Fsca/PublishD | Electro mechanical medical devices |
| 6 | SA-13-02-26-1250 | Alaris™ Point-of-Care Unit (PCU) & BD Alaris™ Point-of-Care Unit (PCU) | CareFusion 303, Inc.. | Becton Dickinson B.V. | https://ade.sfda.go v.sa/Fsca/PublishD | Electro mechanical medical devices |
| 7 | SA-29-03-26-1332 | Dexcom ONE+ iOS App Dexcom G7 iOS / G7 Watch iOS App | DexCom Inc | Bio Standards | https://ade.sfda.go v.sa/Fsca/PublishD | In vitro diagnostic devices |
| 8 | SA-29-03-26-1298 | Medline neuro sponges | Medline Industries Inc..... | Al Amin Medical Instruments Co. Ltd. | https://ade.sfda.go v.sa/Fsca/PublishD | Single-use devices |

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|------------------|------------------|---|----------------------------|---|---|------------------------------------|
| 9 | SA-01-04-26-1339 | EVOQUE Tricuspid Delivery System | Edwards Lifesciences | Arabian Health Care Supply Co. (AHSCC) | https://ade.sfda.gov | Non-active implantable devices |
| 10 | SA-02-04-26-1341 | Swan Ganz catheters | Edwards Lifesciences LLC | ABDULREHMAN AL GOSAIBI GTB | https://ade.sfda.gov v.sa/Fsca/PublishD | Single-use devices |
| 11 | SA-29-03-26-1300 | SX-ELLA Stent Danis (Danis Stent), Danis Procedure Pack – Basic, Danis Procedure Pack | ELLA-CS, s.r.o. | janat al arab trading | https://ade.sfda.gov v.sa/Fsca/PublishD | Non-active implantable devices |
| 12 | SA-31-03-26-1336 | OXOID Agglutinating Sera, Salmonella 9-O | Remel Inc. | Medical supplies & Services Co.Ltd Mediserv | https://ade.sfda.gov | In vitro diagnostic devices |
| 13 | SA-31-03-26-1335 | Infant Child Reduced Energy Electrode, Reduced Energy Electrode Starter Kit | Physio-Control, Inc. | Zimmo Trading Establishment. | https://ade.sfda.gov v.sa/Fsca/PublishD | Electro mechanical medical devices |
| 14 | SA-28-03-26-1293 | HemosIL Heparin Calibrators | Werfen.. | ABDULLA FOUAD HOLDING COMPANY | https://ade.sfda.gov v.sa/Fsca/PublishD | In vitro diagnostic devices |
| 15 | SA-29-08-25-1030 | ACCOLADE Family of Pacemakers and CRT-Ps | Boston Scientific Corp.. | Boston Scientific Gulf for trading LLC | https://ade.sfda.gov | Active Implantable Devices |
| 16 | SA-21-09-25-1062 | CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes | Alcon Laboratories Inc.... | Alcon Pharmaceuticals Ltd | https://ade.sfda.gov v.sa/Fsca/PublishD | Electro mechanical medical devices |