الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector
Surveillance and Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2516 **الرقم المرجعي للتقرير:**

Publish date: 13-Apr-25 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **06-Apr-25** من

To **12-Apr-25** 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=4MT7LEJ3DFP7H8LJ

* Role of contact officer:

- 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.

* مسؤولية ضابط الاتصال:

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

No. of Safety Alerts: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-29-03-25-835	ZOLL Powerheart® G5 AED Product Family	Cardiac Science Corporation	Mohammed Binmahfouz Trading Est	https://ade.sfda.go	Diagnostic and therapeutic radiation devices
2	SA-05-04-25-839	REMISOL Advance (using HL7 host driver)	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.go	In vitro diagnostic devices
3	SA-05-04-25-838	REMISOL Advance	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
4	SA-31-03-25-836	Hugo™ Robotic-Assisted Surgery (RAS)	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.go	Electro mechanical medical devices
5	SA-06-04-25-841	4008 S V10 hemodialysis machine	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ade.sfda.go	Electro mechanical medical devices
6	SA-06-04-25-840	BIOFIRE® Blood Culture Identification 2 (BCID2) Panel	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.go	In vitro diagnostic devices
7	SA-07-04-25-842	072 Aspiration System “Hippo”	Q’Apel Medical, Inc.	Thimar Al Jazirah Healthcare Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
8	SA-08-04-25-843	Alinity m system	Abbott Molecular Inc Sub Abbott Laboratories	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
9	SA-03-04-25-837	Philips CT Big Bore	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-09-04-25-845	Microstream Advance Intubated CO2 Filter Line, VitaLine Intubated CO2 Filter Line and FilterLine Intubated CO2 Filter Line	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/347	Single-use devices
11	SA-09-04-25-846	IntelliSpace Cardiovascular	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software