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: WU2648 — **الرقم المرجعي للتقرير:**

Publish date: 22-Nov-26 — **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **15-Nov-26** من

To **21-Nov-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:

- 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-16-11-26-1653	Aerogen Continuous Nebuliser Tube Set (CNTS) Syringe Pouched - Pack of 5	Aerogen Limited.	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
2	SA-12-11-26-1649	FreeStyle Libre 2 Plus Sensors	Abbott GmbH	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
3	SA-12-11-26-1648	ICD and CRT-D devices	BIOTRONIK UK Ltd	WATEEN MEDICAL CO	https://ade.sfda.gov.sa/Fsca/PublishD	Active Implantable Devices
4	SA-10-11-26-1641	Xpert® MRSA/SA SSTI	Cepheid…	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-10-11-26-1642	MAGNETOM MR Scanners and BIOGRAPH One PET/MR Scanners	SIEMENS	Siemens Medical Solutions	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
6	SA-15-11-26-1652	FIXIT Threaded Anchor, Pre-mounted on a Screwdriver ComposiTCP anchor with two sutures	S.B.M. SAS	Zimmer Biomet Asel Alarabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/3063	Single-use devices
7	SA-16-11-26-1654	Thermo Scientific™ Streptex™ Latex Agglutination Test	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.go	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-16-11-26-1655	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps	Getinge	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
9	SA-15-11-26-1650	Cardiosave Hybrid and Cardiosave Rescue Intra-Aortic Balloon Pumps	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
10	SA-15-11-26-1651	Liquid Assayed Multiqual	Bio-Rad Laboratories Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
11	SA-08-10-26-1582	Philips Azurion Systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices