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: WU2645 — **الرقم المرجعي للتقرير:**

Publish date: 01-Nov-26 — **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 25-Oct-26 من

To 31-Oct-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: 13 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-16-10-26-1591	Positron Emission Tomography and Computed Tomography System	Shanghai United Imaging Healthcare Co., Ltd....	Unifusion Business Service Company	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
2	SA-27-10-26-1613	HeartSine® samaritan® PAD	HeartSine Technologies Ltd..	Zimmo Trading Establishment.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
3	SA-25-10-26-1607	6008 CAREsystem	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
4	SA-27-10-26-1610	Multiple instrument trays	Howmedica Osteonics Corp.	Zimmo Trading Establishment.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
5	SA-18-10-26-1594	FreeStyle Libre 3 app	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-27-10-26-1614	OptiCross Intravascular Ultrasound (IVUS) Imaging Catheters	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
7	SA-22-10-26-1602	VITROS™ Chemistry Products A1c Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.go	In vitro diagnostic devices
8	SA-22-10-26-1605	All Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.go	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-26-10-26-1608	Carestation 850 and 850c Anesthesia Systems	GE Healthcare	GE Healthcare	https://ade.sfda.go	Anaesthetic and respiratory devices
10	SA-28-10-26-1618	Automated Blood Coagulation Analyzer CN-Series analyzers	Sysmex Corporation	Sysmex LLC One Person Co	https://ade.sfda.go	In vitro diagnostic devices
11	SA-26-10-26-1609	Centricity Universal Viewer (UV) and Centricity PACSIW (PACS-IW)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Medical software
12	SA-18-03-26-1286	HF (high-frequency) bipolar cable	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.go	Electro mechanical medical devices
13	SA-15-07-26-1468	Getinge Poladus 150 H1/H2	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices