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: WU2517 — **الرقم المرجعي للتقرير:**

Publish date: 20-Apr-25 — **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **13-Apr-25** من

To **19-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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-13-03-25-814	Anterior Tibialis Tendon, Posterior Tibialis	Musculoskeletal Transplant Foundation, Inc..	ProMedEx	https://ade.sfda.go	Biologically-derived devices
2	SA-10-04-25-847	RAMY Hypodermic Syringe	Alshifa Medical Products Co CJS	alshifa medical syringe	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
3	SA-09-04-25-844	GETINGE AQUADIS 56	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
4	SA-10-04-25-848	Portrait Mobile Patient Monitor Software	GE Healthcare	GE Healthcare	https://ade.sfda.go	Medical software
5	SA-20-03-25-822	OrthoView	Materialise N.V.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	Non-active implantable devices
6	SA-10-04-25-849	Human Assayed MutliSera Level 3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.go	In vitro diagnostic devices
7	SA-13-04-25-854	Welch Allyn Connex Vital Signs Monitor (CVSM), CP150 Electrocardiograph & Connex Spot Monitor Accessory Power Management Stand (APM)	Welch Allyn, Inc.	Baxter AG	https://ade.sfda.gov.sa/Fsca/PublishDetails/355	Hospital hardware
8	SA-14-04-25-855	BD Alaris™ System with Guardrails™ Suite MX	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	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-15-04-25-856	Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
10	SA-13-04-25-853	Liquid Assayed Specific Protein Control Level 1/2/3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.go	In vitro diagnostic devices
11	SA-16-04-25-859	Portrait™ Mobile Monitoring Solution v1.1	GE Healthcare	GE Healthcare	https://ade.sfda.go	Hospital hardware
12	SA-11-04-25-850	Ascenda™ Intrathecal Catheter	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices