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: WU2646 **الرقم المرجعي للتقرير:**

Publish date: 08-Nov-26 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **01-Nov-26** من

To **07-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: 12 **عدد إنذارات السلامة**

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-29-10-26-1620	BLEPHADEMODEX	Laboratories THEA S.A.S	Jamjoom Medicine Store Company Branch Abdul Latif	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
2	SA-29-10-26-1622	LithoVue Elite StoneSmartTM Connect Console Power Adaptor	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.go	Reusable devices
3	SA-03-11-26-1626	ES2® Spinal System Nitinol K-Wire Blunt	Stryker Spine.	Zimmo Trading Establishment.	https://ade.sfda.go	Non-active implantable devices
4	SA-03-11-26-1627	Horizon® DXA systems	Hologic Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
5	SA-03-11-26-1628	Uterine Curette	KLS Martin GmbH + Co. KG	International Medical Supplies Company	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
6	SA-29-10-26-1621	Incisive CT system	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
7	SA-04-11-26-1629	Multiple Instruments	Beckman Coulter Inc..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
8	SA-02-11-26-1625	Aptiva CTD Essential Reagent	INOVA Diagnostics, Inc.	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
9	SA-28-10-26-1619	COULTER DxH Diluent	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-02-11-26-1623	Salinose SYMBIOFILM Child (Salinose Symbiofilm Isotonic Saline Solution 0.9%, 100 mL)	Lallemand Pharma AG	Middle East Pharmaceutical Industries Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
11	SA-05-11-26-1633	Salinose SYMBIOFILM Adult (Salinose Symbiofilm hypertonic Saline Solution 2.2%)	Lallemand Pharma AG	Middle East Pharmaceutical Industries Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
12	SA-04-11-26-1630	Multiple Philips MR Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices