



**Safety Alerts Weekly Update**

**Report Reference:**

WU2602

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04-Jan-26

**التقرير الأسبوعي لإذارات السلامة**

الرقم المرجعي للتقرير:

تاريخ النشر:

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

From 28-Dec-25 من  
To 03-Jan-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 متاثر بأي من إذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متاثر بأي من إذارات السلامة.

لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتاثرة، الرجاء فتح رابط إنذار السلامة:



No. of Safety Alerts: 5 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-31-12-25-1203	EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 and EliA™ ANA Positive Control 200	ThermoFisher.	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/684">https://ade.sfda.gov.sa/Fsca/PublishDetails/684</a>	In vitro diagnostic devices
2	SA-28-12-25-1201	NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbit Company	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/684">https://ade.sfda.gov.sa/Fsca/PublishDetails/684</a>	Anaesthetic and respiratory devices
3	SA-28-12-25-1200	Sentinel Seal™, Altitude™, Aqua-Seal™, ThoraSeal™ Chest Drainage Units & accessories	Cardinal Health 200, LLC..	Medical Regulations Gate	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/684">https://ade.sfda.gov.sa/Fsca/PublishDetails/684</a>	Single-use devices
4	SA-30-12-25-1202	Bubble Sensor	MAQUET Cardiopulmonary GmbH	Medical Elements	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/684">https://ade.sfda.gov.sa/Fsca/PublishDetails/684</a>	Electro mechanical medical devices
5	SA-25-12-25-1199	SMSCOZYM SPONGES	Saudi Medical Solution Company	Saudi Medical Solution Company	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/684">https://ade.sfda.gov.sa/Fsca/PublishDetails/684</a>	Single-use devices