

### Safety Alerts Weekly Update

Report Reference: WU2439  
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### التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:  
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 15-Sep-24  
To 21-Sep-24

من  
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=CTLNDA7ARTRDHMA>



\* 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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إبذار 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-16-09-24-597	Alinity m System, Alinity m HR HPV AMP Kit & Alinity m STI AMP Kit	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
2	SA-28-08-24-574	Allurion Device / Elipse Gastric Balloon System	Allurion technologies inc..	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Non-active implantable devices
3	SA-15-09-24-591	Centricity Universal Viewer Zero Footprint Client.	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Diagnostic and therapeutic radiation devices
4	SA-13-09-24-588	Enterprise Imaging XERO Viewer	AGFA Corp.	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices
5	SA-16-09-24-596	Fluoroscopic Sonialvision G4	Shimadzu Corporation	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices
6	SA-15-09-24-593	Giraffe OmniBed and Giraffe OmniBed Carestation devices	Datex - Ohmeda Inc	GE Healthcare	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Electro mechanical medical devices
7	SA-15-09-24-592	MEERA CL	MAQUET Inc	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
8	SA-16-09-24-595	Microalbumin Calibrator series (mALB CAL).	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-18-09-24-600	Olympus BF-H1100 and BF-1TH1100 Bronchovideoscopes, and Olympus EVIS EXERA III SIF-H190 Small Intestinal Videoscope	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/115">https://ade.sfda.gov.sa/Fsca/PublishDetails/115</a>	Electro mechanical medical devices
10	SA-15-09-24-594	-SOLTIVE Pro SuperPulsed Laser System - SOLTIVE Premium SuperPulsed Laser System	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/108">https://ade.sfda.gov.sa/Fsca/PublishDetails/108</a>	Diagnostic and therapeutic radiation devices
11	SA-14-09-24-589	Spaceplus Perfusor	B. Braun Melsungen AG.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/115">https://ade.sfda.gov.sa/Fsca/PublishDetails/115</a>	Electro mechanical medical devices
12	SA-22-11-23-165	Trilogy Evo and Trilogy Evo O2 Ventilators	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/115">https://ade.sfda.gov.sa/Fsca/PublishDetails/115</a>	Anaesthetic and respiratory devices
13	SA-14-09-24-590	Xpert Xpress CoV-2 plus	Cepheid...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/115">https://ade.sfda.gov.sa/Fsca/PublishDetails/115</a>	In vitro diagnostic devices