

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:** WU2544  
**Publish date:** 26-Oct-25

**الرقم المرجعي للتقرير:**  
**تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 19-Oct-25  
To 25-Oct-25

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=4MT7LEJ3DFP7H8LI>



**\* Role of contact officer:**

**\* مسؤولية ضابط الاتصال:**

- 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.

- 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: 14 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-27-08-25-1026	Ultra IABP Catheter Kit	Insightra Medical Inc	Distinguished Medical World	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
2	SA-12-10-25-1090	Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Active Implantable Devices
3	SA-19-10-25-1099	IH-500	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
4	SA-16-10-25-1097	SnareMaster Plus Hot/Cold 10mm and 15mm	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
5	SA-21-10-25-1103	DVI display cables	Spacelabs Healthcare 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
6	SA-20-10-25-1101	EASY PULSE	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
7	SA-19-10-25-1100	Evis Exera III Duodenovideoscope. Evis Lucera Elite Duodenovideoscope. Duodenovideoscope.	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> <a href="https://ade.sfda.gov.sa/Fsca/PublishD">etails/590</a>	Reusable devices
8	SA-21-10-25-1104	ShockPulse Lithotripsy Transducer	Olympus Corporation of the Americas .	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

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-22-10-25-1105	Alinity m HIV-1 AMP Kit	Abbott Molecular Division Inc.	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
10	SA-23-10-25-1106	Multiva 1.5T MR Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices
11	SA-24-10-25-1108	Philips CT Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices
12	SA-08-05-24-402	HA FlexTrak Trolley	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Hospital hardware
13	SA-20-10-25-1102	Medtronic Signia™ Small Diameter Curved Tip Intelligent Reload	Covidien LLC....	Medtronic Saudi Arabia	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
14	SA-06-06-24-446	Sense XL Torso Coil	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Diagnostic and therapeutic radiation devices