

### Safety Alerts Weekly Update

### التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2620

الرقم المرجعي للتقرير:

Publish date:

10-May-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 03-May-26

من

To 09-May-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:

\* 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 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 إنذار السلامة:

No. of Safety Alerts: 8 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-03-05-26-1379	Adapter for Head Positioning	Baxter Healthcare	Baxter AG	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/810">https://ade.sfda.gov.sa/Fsca/PublishDetails/810</a>	Hospital hardware
2	SA-03-05-26-1380	da Vinci® 5 (dV5) System equipped with the Near Infrared (NIR) Handheld Camera	Intuitive Surgical Inc	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/810">https://ade.sfda.gov.sa/Fsca/PublishDetails/810</a>	Electro mechanical medical devices
3	SA-04-05-26-1381	Giraffe OmniBed and Giraffe OmniBed Carestation Devices	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Electro mechanical medical devices
4	SA-05-05-26-1386	Human Assayed Mutli-Sera Level 3	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
5	SA-05-05-26-1383	Zenition 10 and Zenition 30	Philips Medical Systems Nederland B.V.	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
6	SA-05-05-26-1384	Philips Azurion and Allura Systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Diagnostic and therapeutic radiation devices
7	SA-05-05-26-1382	Genius" Review Station	Hologic Inc.	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
8	SA-06-05-26-1387	Vivalytic STI Cartridges	Bosch Healthcare Solutions GmbH	Binary System Medical Co	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices