

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإبذارات السلامة**

**Report Reference:**

**WU2431**

الرقم المرجعي للتقرير:

**Publish date:**

**28-Jul-24**

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From

**21-Jul-24**

من

To

**27-Jul-24**

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-21-07-24-520	Access HBc Ab	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
2	SA-18-07-24-516	ACL TOP 350 CTS- ACL TOP 750 CTS	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
3	SA-23-07-24-527	All Randox RX/Evidence Analysers	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
4	SA-18-07-24-517	BD BACTEC™ MGIT™ 960 PZA Kit	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
5	SA-17-07-24-514	BioFire® FilmArray® Gastrointestinal (GI) Panel	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
6	SA-16-07-24-513	Horizon DXA System	Hologic Inc	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
7	SA-21-07-24-518	Immunoassay Speciality I – Level 3	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
8	SA-12-06-24-458	MRI Systems	Canon Inc	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
9	SA-22-07-24-526	NOVOSYN CHD	B Braun Surgical SA	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-21-07-24-519	RX Daytona Plus (with ISE/without ISE)	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/33">https://ade.sfda.gov.sa/Fsca/PublishDetails/33</a>	In vitro diagnostic devices
11	SA-21-07-24-522	VITEK 2 Software	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/33">https://ade.sfda.gov.sa/Fsca/PublishDetails/33</a>	In vitro diagnostic devices
12	SA-22-07-24-524	VITROS Immunodiagnostic Products	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/33">https://ade.sfda.gov.sa/Fsca/PublishDetails/33</a>	In vitro diagnostic devices
13	SA-10-07-24-504	Ziehm hand switch #88036 Version 1.02 for the device type: Ziehm 8000 Ziehm Solo, Ziehm Solo FD Ziehm Vision, Ziehm Vision FD Ziehm Vision R, Ziehm Vision RFD, Ziehm Vision RFD 3D	Ziehm Imaging GmbH.	Saudi Health Services Co. Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/33">https://ade.sfda.gov.sa/Fsca/PublishDetails/33</a>	Diagnostic and therapeutic radiation devices