

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإبذارات السلامة**

**Report Reference:**

**WU2419**

الرقم المرجعي للتقرير:

**Publish date:**

**05-May-24**

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From

**28-Apr-24**

من

To

**04-May-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 إنذار السلامة:

No. of Safety Alerts: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-29-04-24-386	HeartSine Samaritan PAD	HeartSine Technologies Ltd	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
2	SA-22-04-24-376	ARDS Array, DOA Blood Array, DOA Urine Array, DOA Urine Array II	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
3	SA-29-04-24-387	CARESCAPE B850□ Carescape Monitor B650□ Carescape Canvas 1000 CARESCAPE Canvas Smart Display	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=2102">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=2102</a>	Electro mechanical medical devices
4	SA-14-03-24-325	DIAGNOSTIC ULTRASOUND SYSTEM	Toshiba Medical Systems Corporation	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Diagnostic and therapeutic radiation devices
5	SA-28-04-24-383	Evidence MultiSTAT	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
6	SA-22-04-24-375	Human Assayed Multi-Sera Level 3.	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
7	SA-29-04-24-389	IACS Monitoring with C500 Model: Infinity M500 Docking Station	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices

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8	SA-28-04-24-384	Medartis APTUS TriLock Screw	Medartis AG.	ProMedEx	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Ophthalmic and optical devices
9	SA-25-04-24-382	MR systems terminal connections in the general Mains Distribution Unit (g-MDU)	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Diagnostic and therapeutic radiation devices
10	SA-23-04-24-379	Multichem S Plus, Multichem IA Plus, Multichem P	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
11	SA-25-04-24-381	PERLA TL 25D SCREW device	SPINEART	Tina Medix Technologies Int. Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Non-active implantable devices
12	SA-28-04-24-385	Vaporizer Sevoflurane, QUIK FIL,Vaporizer Isoflur, Maquet filling	Getinge Lancer	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices