

### Safety Alerts Weekly Update

Report Reference: WU2426  
Publish date: 23-Jun-24

### 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 09-Jun-24  
To 22-Jun-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=CTLNDA7ARTRDHM>



\* 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 إذار 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	EA4AB52CBE2D3	Aqualine family of tubing sets for Aquarius System	Haemotronic	Arabian Health Care Supply Co. (AHSCC)	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Single-use devices
2	SA-12-06-24-459	ARTIS icono systems with small detector and the according collimator	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Diagnostic and therapeutic radiation devices
3	SA-10-06-24-451	Bivona Aire-Cuf, TTS, Uncuffed, Mid-Range Neonatal/Pediatric Tracheostomy Tube(s) and Bivona Aire-Cuf, TTS, Cuffless FlexTend, TTS FlexTend Adult Tracheostomy Tube(s)	Smiths Medical International Limited	almdar medical Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=21079">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=21079</a>	Single-use devices
4	SA-06-06-24-445	Captus 4000e Thyroid Uptake System	Mirion Technologies (Capintec), Inc.	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Diagnostic and therapeutic radiation devices
5	SA-10-06-24-454	Centrella and Pro+ Mattress Replacement System (MRS)	Hill Rom Inc	Medical regulations gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Healthcare facility products and adaptations
6	SA-09-06-24-449	DEFIGARD HD-7	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Electro mechanical medical devices
7	SA-10-06-24-455	Infinity DBS neurostimulation System	Abbott..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Active Implantable Devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-10-06-24-452	IntelliVue Multi-Measurement Module X3	Philips Medizin Systeme GmbH	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Electro mechanical medical devices
9	SA-10-06-24-456	Proclaim, Proclaim XR, Proclaim Elite SCS System and Proclaim DRG Neurostimulation System	Abbott..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Active Implantable Devices
10	SA-06-06-24-447	QIAcube Connect MDx instrument	QIAGEN Ltd	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	In vitro diagnostic devices
11	SA-06-06-24-446	Sense XL Torso Coil	Philips Medical Systems	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
12	SA-06-06-24-448	Stryker Mako 3.0 and 3.1	Stryker Orthopaedics	Zimmo Trading Establishment.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Electro mechanical medical devices
13	SA-12-11-23-150	Turbo V and IonDrive Turbo V source	AB SCIEX	Dar Al-Zahrawi Medical Co. LLC	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	In vitro diagnostic devices
14	SA-11-06-24-457	VITROS Chemistry Products FS Diluent Pack 3	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	In vitro diagnostic devices