

### Safety Alerts Weekly Update

Report Reference: WU2414  
Publish date: 31-Mar-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 24-Mar-24  
To 30-Mar-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: 18 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-21-03-24-337	Alinity m System	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
2	SA-25-03-24-344	Arterial Cannulae, Venous Cannulae, Suction Tubes, Intracoronary Shunts, Aortic Root Cannulae and Cardioplegia Needles	Medtronic Inc.	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=209">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=209</a>	Single-use devices
3	SA-25-03-24-342	Artis Zee, Zeego, Q, Q.zen Systems	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
4	SA-26-03-24-346	Astral 100/150 ventilator	ResMed Limited.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Anaesthetic and respiratory devices
5	SA-21-03-24-339	BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Anaesthetic and respiratory devices
6	SA-20-03-24-331	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
7	SA-22-03-24-340	EXPO Angiographic Catheter	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Single-use devices
8	SA-21-03-24-334	HeartMate 3 LVAS Kits	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
9	SA-27-03-24-350	Liquid Protein Calibrators. C3 and Haptoglobin liquid protein calibrators used with Randox IgA, IgG, and IgM assays	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	In vitro diagnostic devices
10	SA-25-03-24-343	Multiva 1.5T	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Diagnostic and therapeutic radiation devices
11	SA-21-03-24-338	OmniLab Advanced + (OLA+)	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Anaesthetic and respiratory devices
12	SA-27-03-24-349	Power Supply (UPS) devices supporting the Patient Information Center (PIC) iX system	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Electro mechanical medical devices
13	SA-24-03-24-341	Redux Electrolyte Crème	Parker Laboratories, Inc...	United Medical Industries Co Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Single-use devices
14	SA-17-03-24-328	RF-32 ROTAFLOW Centrifugal Pump	MAQUET Cardiopulmonary GmbH	Medical Elements	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Single-use devices
15	SA-27-03-24-353	Stay Safe Catheter Extension Luer-Lock 25cm, 32cm & 40cm	Fresenius Medical Care.	Fresenius Medical Care GmbH	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Single-use devices
16	SA-13-03-24-324	TFNA Femoral Nail	Synthes GmbH.	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Non-active implantable devices
17	SA-25-03-24-345	Ureteral dilator	Coloplast	janat al arab trading	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Single-use devices
18	SA-20-03-24-333	Vantage Titan, Vantage Elan, Vantage Orian, Vantage Fortian	Canon Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	Diagnostic and therapeutic radiation devices