

### Safety Alerts Weekly Update

Report Reference: WU2625  
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### التقرير الأسبوعي لإنذارات السلامة

الرقم المرجعي للتقرير:  
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 07-Jun-26 من  
To 13-Jun-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:

- 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 إنذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إنذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إنذار 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	SA-09-06-26-1428	IMMULITE 2000 and IMMULITE 2000 Xpi	Siemens Healthcare Diagnostics Inc.	HIGH STANDARD MEDICAL INC	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	In vitro diagnostic devices
2	SA-04-06-26-1418	VITROS™ Chemistry Products SALI Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	In vitro diagnostic devices
3	SA-31-05-26-1411	BeneHeart D1 Automated External Defibrillator (AED)	Shenzhen Mindray Bio-Medical Electronics Co.,	Dar Batterjee Company Ltd	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	Electro mechanical medical devices
4	SA-07-06-26-1424	elisa 300/500/600/600 R-VIT/800/800 R-VIT/800	Lowenstein Medical GmbH &Co.KG	Bio Standards	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	Anaesthetic and respiratory devices
5	SA-08-06-26-1426	Breathing circuit set, coaxial	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Anaesthetic and respiratory devices
6	SA-07-06-26-1420	Dimension clinical chemistry system	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	In vitro diagnostic devices
7	SA-05-06-26-1419	Abiomed Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	Electro mechanical medical devices
8	SA-07-06-26-1423	One-Piece Guedel Airways	Intersurgical Limited	Al Hammad Medical Services	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Anaesthetic and respiratory devices
9	SA-08-06-26-1427	Optima XR200/220/240amx systems	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.go">https://ade.sfda.go</a>	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-09-06-26-1429	Copper (R1b Reagent), Copper	Randox Laboratories Ltd.	Bio Standards	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
11	SA-09-06-26-1430	Key Gel	National Pharmaceuticals Factory Co	National Pharmaceuticals Factory Co	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Healthcare facility products and adaptations
12	SA-11-06-26-1433	Thermo Scientific™ Sensititre ARIS HiQ Firmware	Trek Diagnostic Systems Ltd.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
13	SA-30-06-25-946	Philips MR Systems	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
14	SA-08-06-26-1425	Giraffe and Panda warmer with Integrated Resuscitation System (iRes) and Giraffe Stand-alone Infant Resuscitation System	Datex - Ohmeda Inc	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/854">https://ade.sfda.gov.sa/Fsca/PublishDetails/854</a>	Electro mechanical medical devices