

### Safety Alerts Weekly Update

Report Reference: WU2435  
Publish date: 25-Aug-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 18-Aug-24  
To 24-Aug-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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-18-08-24-561	ACUSON Juniper and ACUSON Maple Ultrasound systems	Siemens Medical Solutions	Siemens Medical Solutions	<a href="https://ade.sfda.g">https://ade.sfda.g</a>	Diagnostic and therapeutic radiation devices
2	SA-20-08-24-566	ACUSON Redwood Ultrasound system	Siemens Medical Solutions	Siemens Medical Solutions	<a href="https://ade.sfda.g">https://ade.sfda.g</a>	Diagnostic and therapeutic radiation devices
3	SA-19-08-24-565	Atellica CH/CI Analyzer	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a>	In vitro diagnostic devices
4	SA-19-08-24-563	BD Alaris System	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a>	Electro mechanical medical devices
5	SA-22-04-24-378	High Flow Insufflation Unit	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a>	Electro mechanical medical devices
6		Hookup	STERIS Corporation....	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a>	Hospital hardware
7	SA-15-08-24-559	Latham bowl	Haemonetics Corp.	Arabian Trade House Est.	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a>	Laboratory equipment
8	SA-04-08-24-543	Level 1 Fast Fluid Flow Fluid Warmers and Level 1 NORMOFLO Irrigation Fluid Warmers	Smiths Medical International Limited	almdar medical Est.	<a href="https://ade.sfda.g">https://ade.sfda.g</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish">ov.sa/Fsca/Publish</a> <a href="https://ade.sfda.gov.sa/Fsca/Publish/Details/79">Details/79</a>	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-20-08-24-567	Vanta™ Implantable Neurostimulator	Medtronic Inc.	Medtronic Saudi Arabia	<a href="https://ade.sfda.g">https://ade.sfda.g</a>	Active Implantable Devices