

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2637
Publish date: 06-Sep-26

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 30-Aug-26
To 05-Sep-26

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=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: 15 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-02-09-26-1542	Atellica CH and Atellica CI analyzers	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
2	SA-31-08-26-1534	VentStar Resus Neo and VentStar Resuscitaire	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
3	SA-26-08-26-1526	NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbits Company	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
4	SA-01-09-26-1536	VICTO	Promedon S.A..	Tart Medical	https://ade.sfda.gov.sa/Fsca/PublishD	Non-active implantable devices
5	SA-02-09-26-1541	SACO - Ultrasound Gel	SAHHA FACTORY COMPANY FOR SOLUTION	SAHHA FACTORY COMPANY FOR SOLUTION MEDICAL	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
6	SA-30-08-26-1531	Monitor	Shenzhen Mindray Bio-Medical Electronics Co.,	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
7	SA-30-08-26-1532	DxC 500i Clinical Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
8	SA-31-08-26-1535	DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
9	SA-01-09-26-1537	Magnetic Resonance (MR) imaging systems with Diffusion Tensor Imaging (DTI)	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-02-09-26-1540	External Waste Pump (accessory for the Alinity ci-series and ARCHITECT Systems)	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	Laboratory equipment
11	SA-31-08-26-1533	Incisive CT and CT 5300	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
12	SA-20-01-26-1227	da Vinci X and Xi Reusable Instruments with Jaws	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Reusable devices
13	SA-08-06-26-1426	Breathing circuit set, coaxial	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
14	SA-18-01-26-1217	Grip Cable Failures on da Vinci S and Si Reusable Instruments with Jaws	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
15	SA-02-09-26-1538	Philips iCT, Ingenuity CT, and Brilliance CT 64 systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices