

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2522

الرقم المرجعي للتقرير:

Publish date: 25-May-25

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 18-May-25

من

To 24-May-25

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=4MT7LEJ3DFP7H8LJ>



* Role of contact officer:

* مسؤولية ضابط الاتصال:

- 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.

- 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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-15-05-25-892	Reciprocating & Sternum Saws	Stryker Instruments.	Zimmo Trading Establishment.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
2	SA-15-05-25-893	ORTHO VISION® and ORTHO VISION® Max analyzers	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov	In vitro diagnostic devices
3	SA-19-05-25-896	ENDOPATH ECHELON™ Vascular White Reload for Advanced Placement Tip (35 mm, 4 Row)	Ethicon Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/400	Reusable devices
4	SA-20-05-25-900	Drive DeVilbiss Healthcare Car Charger Power Cord Accessory	Drive DeVilbiss	Bio Standards	https://ade.sfda.gov	Anaesthetic and respiratory devices
5	SA-11-05-25-887	Chek-Stix® UA Diptube Liquid QC	Siemens Healthcare Diagnostics Inc..	ARABIAN MEDICAL & PHARMACEUTICAL CO.	https://ade.sfda.gov	In vitro diagnostic devices
6	SA-12-05-25-888	Liquid Urine Control – Level 2 and Assayed Urine Control – Level 3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
7	SA-15-05-25-891	Evis Exera III Duodenovideoscope (TJF-Q190V), Evis Lucera Elite Duodenovideoscope (TJF-Q290V), Duodenovideoscope (TJF-Q170V)	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/395	Electro mechanical medical devices
8	SA-16-05-25-894	Wireless foot switch used with the Philips Zenition 50, Zenition 70, and Veradius Unity systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/397	Diagnostic and therapeutic radiation devices
9	SA-18-05-25-895	SOLTIVE™ Premium SuperPulsed Laser System	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/397	Electro mechanical medical devices
10	SA-19-05-25-897	Sophie 2020	Fritz Stephan GmbH.	Al Khateeb United Trading Est.	https://ade.sfda.gov.sa/Fsca/PublishDetails/397	Anaesthetic and respiratory devices
11	SA-20-05-25-898	BD Insyte Autoguard Shielded IV Catheter	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/397	Single-use devices
12	SA-20-05-25-899	BD BACTEC™ MGIT™ 960 PZA Kit	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/397	Laboratory equipment