

Safety Alerts Weekly Update

Report Reference: WU26 14
Publish date: 29-Mar-26

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 15-Mar-26 من
To 28-Mar-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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-12-03-26-1280	1.0MM and 1.5MM Fine Round Diamond Bur	Stryker Instruments.	Zimmo Trading Establishment.	https://ade.sfda.go	Single-use devices
2	SA-25-03-26-1287	EDAN Patient Monitoring and Fetal Monitoring Devices.	Edan Instruments Inc...	Medical Regulations Gate	https://ade.sfda.go	Electro mechanical medical devices
3	SA-18-03-26-1285	SOLTIVE Superpulsed Laser System	Gyrus ACMI, Inc.	Gulf Medical Co.	https://ade.sfda.go	Diagnostic and therapeutic radiation devices
4	SA-09-03-26-1279	BD Kiestra™ ReadA	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.go/v.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-17-03-26-1282	Access Total T4 Calibrators	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.go/v.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-18-03-26-1286	HF (high-frequency) bipolar cable	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.go	Electro mechanical medical devices
7	SA-25-03-26-1288	PALAMIX® uno and PALAMIX® duo	Heraeus Medical GmbH	Al Amin Medical Instruments Co. Ltd.	https://ade.sfda.go	Anaesthetic and respiratory devices
8	SA-17-03-26-1284	Leksell® Vantage Arc System	Elekta Inc	Medical Regulations Gate	https://ade.sfda.go/v.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
9	SA-17-03-26-1283	IVascular navitian	Life Vascular Devices Biotech S.L	Saudi Sicli Company	https://ade.sfda.go/v.sa/Fsca/PublishD	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-15-12-25-1181	Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.go	Active Implantable Devices
11	SA-15-03-26-1281	Instinct Plus Endoscopic Clipping Device	Wilson-Cook Medical Inc.	ARABIAN MEDICAL & PHARMACEUTICAL CO.	https://ade.sfda.go	Single-use devices
12	SA-24-06-24-468	BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices