الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector
Surveillance and Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2605 — **الرقم المرجعي للتقرير:**

Publish date: 25-Jan-26 — **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **18-Jan-26** من

To **24-Jan-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: 15 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-15-01-26-1215	AlignRT InBore	Vision RT Ltd..	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
2	SA-19-01-26-1224	ShockPulse-SE Lithotripsy System	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.go	Electro mechanical medical devices
3	SA-19-01-26-1221	Olympus resection/inner sheaths of resectoscopes.	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.go	Electro mechanical medical devices
4	SA-19-01-26-1225	KWIK-STIK 6-Pack, KWIK-STIK 2-Pack, LYFO DISK	Microbiologics Inc.	Medical Regulations Gate	https://ade.sfda.go	In vitro diagnostic devices
5	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
6	SA-18-01-26-1220	Panocell®-20	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-19-01-26-1223	Centricity Universal Viewer Zero Footprint Client (ZFP)	GE Healthcare	GE Healthcare	https://ade.sfda.go	Medical software
8	SA-20-01-26-1228	da Vinci S and Si Tenaculum Forceps and Permanent Cautery Hook	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-20-01-26-1226	Alaris VP Infusion Sets	BD Switzerland Sarl	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
10	SA-22-01-26-1232	Medline Kits containing Surgical Gowns, Packs, and Drapes	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
11	SA-18-01-26-1219	ShockPulse Lithotripsy Transducer	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.go	Diagnostic and therapeutic radiation devices
12	SA-19-01-26-1222	ViziShot 2 FLEX (19G)	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
13	SA-16-01-26-1216	Tenaculum Forceps - Small Graptor on da Vinci X and Xi Tenaculum Forceps and Small Graptor	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/696	Reusable devices
14	SA-20-01-26-1227	da Vinci X and Xi Reusable Instruments with Jaws	Intuitive Surgical Inc	Gulf Medical Co.	https://ade.sfda.go	Reusable devices
15	SA-21-01-26-1230	Automated Compounding Device Inlet	Baxter Healthcare	Baxter AG	https://ade.sfda.go	Single-use devices