

### Safety Alerts Weekly Update

### التقرير الأسبوعي لإنذارات السلامة

Report Reference:

WU2621

الرقم المرجعي للتقرير:

Publish date:

17-May-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 10-May-26

من

To 16-May-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:

\* 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: 7 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-11-05-26-1388	TCN (Thermo Couple Nitinol) and CSK (Cosman Straight Kit)	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	Single-use devices
2	SA-11-05-26-1389	AW Server 3.2 ext. 6.5	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	Medical software
3	SA-05-05-26-1385	Alinity hq	Abbott GmbH	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	In vitro diagnostic devices
4	SA-12-05-26-1390	Medline Red Rubber Intermittent Catheters and Medline Red Rubber Intermittent Catheter Trays	Medline Industries Inc	Thimar Al Jazirah Healthcare Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	Single-use devices
5	SA-14-05-26-1391	MERLIN™ 3650 PATIENT CARE SYSTEM (PCS)	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	Electro mechanical medical devices
6	SA-14-05-26-1392	ORTHO CONNECT	Biomedical Data Solutions Ltd.	Samir Photographic Supplies Co. Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	In vitro diagnostic devices
7	SA-12-11-25-1143	Single Use Ligating Device PolyLoop	Olympus Europa SE & CO.KG..	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/821">https://ade.sfda.gov.sa/Fsca/PublishDetails/821</a>	Single-use devices