

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:** WU2640

الرقم المرجعي للتقرير:

**Publish date:** 27-Sep-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 20-Sep-26

من

To 26-Sep-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: 11 عدد إنذارات السلامة

| Safety Alert No. | NCMDR Ref.       | Medical Device                                                                        | Manufacturer             | Authorized Representative /Importer            | Link                                                                                      | Medical Device Category                      |
|------------------|------------------|---------------------------------------------------------------------------------------|--------------------------|------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------|
| 1                | SA-19-09-26-1558 | Covidien Auto Suture™<br>Structural Balloon Trocar &<br>Auto Suture™ Blunt Tip Trocar | Covidien LLC....         | Medtronic Saudi Arabia                         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Single-use devices                           |
| 2                | SA-20-09-26-1559 | cobas c 303 Analytical Unit and<br>cobas c 303 Analytical Unit-EMC                    | Roche Diagnostics GmbH.  | Roche Diagnostics Saudi Arabia Limited         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | In vitro diagnostic devices                  |
| 3                | SA-21-09-26-1562 | PENTAX Medical ultrasound<br>endoscopes and<br>water bottle assembly                  | Hoya Corporation         | Medical supplies & Services<br>Co.Ltd Mediserv | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices           |
| 4                | SA-18-09-26-1557 | Amplatzer Amulet Left Atrial<br>Appendage Occluder                                    | Abbott Medical           | Medical Regulations Gate                       | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Non-active implantable devices               |
| 5                | SA-17-09-26-1556 | Arjo Carevo shower trolley                                                            | Arjo Huntleigh           | Al-Faisaliah Medical System                    | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Hospital hardware                            |
| 6                | SA-21-09-26-1561 | Direxion and Direxion HI-FLO                                                          | Boston Scientific Corp.. | Boston Scientific Gulf for trading LLC         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Single-use devices                           |
| 7                | SA-23-09-26-1563 | InterStim™ SureScan™ MRI leads                                                        | Medtronic Inc.           | Medtronic Saudi Arabia                         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Active Implantable Devices                   |
| 8                | SA-08-09-26-1547 | IOMAX Cortical Module                                                                 | Cadwell Industries, Inc. | Al Amin Medical Instruments Co. Ltd.           | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Healthcare facility products and adaptations |

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|------------------|------------------|-------------------------------------------|---------------------------------------|-------------------------------------|-------------------------------------------------------------------------------------------|------------------------------------|
| 9                | SA-17-09-26-1555 | SOLTIVE™ Premium SuperPulsed Laser System | Olympus Corporation of the Americas . | Gulf Medical Co.                    | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices |
| 10               | SA-15-07-26-1468 | Getinge Poladus 150 H1/H2                 | Getinge Disinfection AB               | Gulf Medical Co.                    | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices |
| 11               | SA-21-07-26-1477 | Portrait Core Services software           | GE Healthcare                         | GE Healthcare                       | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Medical software                   |