

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2551

الرقم المرجعي للتقرير:

Publish date: 14-Dec-25

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 07-Dec-25

من

To 13-Dec-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: 8 عدد إنذارات السلامة

| Safety Alert No. | NCMDR Ref.       | Medical Device                                          | Manufacturer                                    | Authorized Representative /Importer    | Link                                                                                      | Medical Device Category                      |
|------------------|------------------|---------------------------------------------------------|-------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------|
| 1                | SA-10-12-25-1174 | HP Flex Pro-C PCs used with the Sensis Vibe application | Siemens Healthcare GmbH                         | Siemens Medical Solutions              | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices           |
| 2                | SA-07-12-25-1169 | MINOP TROCAR                                            | Aesculap...                                     | ProMedEx                               | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices           |
| 3                | SA-07-12-25-1168 | cobas c 703 Analytical Unit                             | 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                  |
| 4                | SA-08-12-25-1171 | Philips Azurion R3.0 Systems                            | Philips Medical Systems                         | Philips Healthcare Saudi Arabia Ltd.   | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Diagnostic and therapeutic radiation devices |
| 5                | SA-08-12-25-1170 | Riptide™ Aspiration Tubing                              | Micro Therapeutics Inc (DBA ev3 Neurovascular ) | Medtronic Saudi Arabia                 | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Single-use devices                           |
| 6                | SA-09-12-25-1173 | Serology ToRCH IgM Positive Control                     | Randox Laboratories Ltd.                        | Bio Standards                          | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | In vitro diagnostic devices                  |
| 7                | SA-10-12-25-1176 | Vanta™ Clinician Programmer Application                 | Medtronic Inc.                                  | Medtronic Saudi Arabia                 | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Medical software                             |
| 8                | SA-09-12-25-1172 | Corpuls3 Touch                                          | GS Elektromedizinische Geräte G. Stemple GmbH   | Al Khateeb United Trading Est.         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> | Electro mechanical medical devices           |