

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:**

**WU2616**

**الرقم المرجعي للتقرير:**

**Publish date:**

**12-Apr-26**

**تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **05-Apr-26**

من

To **11-Apr-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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-08-04-26-1347	IMMULITE 2000 & IMMULITE 2000 Xpi	Siemens Healthcare Diagnostics Inc.	HIGH STANDARD MEDICAL INC	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
2	SA-02-04-26-1342	AneurysmFlow	Philips Healthcare	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
3	SA-06-04-26-1345	Dimension Clinical Chemistry System	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices
4	SA-04-04-26-1343	Getinge Steam Sterilizers	Getinge Sterilization AB	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Hospital hardware
5	SA-31-03-26-1334	STA NeoPTimal 5	Diagnostica Stago S.A.S.	Diagnostic Saudi Arabia Trading Company	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
6	SA-05-04-26-1344	Intra uterine tube with 4 mm diameter	Nucletron bv	Medical regulations gate	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	Reusable devices
7	SA-26-03-26-1290	Impella Purge Cassette	ABIOMED Inc	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
8	SA-06-04-26-1346	Sodium Bicarbonate	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
9	SA-08-04-26-1348	Panocell® -16 , Capture-R® ReadyID Extend II	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov">https://ade.sfda.gov</a>	In vitro diagnostic devices