

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference:

WU2636

الرقم المرجعي للتقرير:

Publish date:

30-Aug-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **23-Aug-26**

من

To **29-Aug-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:



Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

No. of Safety Alerts: 14 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-23-08-26-1516	StrykeFlow PS and AHTO Tube Set	Stryker Neurovascular...	Zimmo Trading Establishment.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1937	Electro mechanical medical devices
2	SA-20-08-26-1514	medin-NC3	medin Medical Innovations GmbH	Anfas Arabia Trading Company	https://ade.sfda.gov.sa/Fsca/PublishDetails/1937	Anaesthetic and respiratory devices
3	SA-23-08-26-1518	Blanketrol III Hyper-Hypothermia System, Blanketrol II HyperHypothermia System AND Innercool CoolBlue devices	Gentherm Medical, LLC.	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishDetails/1937	Electro mechanical medical devices
4	SA-20-08-26-1513	IPV Systems (IPV 1; IPV-1C; IPV-2C; Impulsator; Travel Air; IPV-HC)	Percussionaire Corporation.	Techno Orbits Company	https://ade.sfda.gov.sa/Fsca/PublishDetails/1938	Anaesthetic and respiratory devices
5	SA-23-08-26-1515	BD Alaris™ System Pump Infusion Sets compatible with BD Alaris™ System Pump Module 8100	CareFusion 303, Inc..	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1938	Electro mechanical medical devices
6	SA-23-08-26-1517	BD Phoenix™ CPO Detect 6-well panel	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1938	Laboratory equipment
7	SA-23-08-26-1519	VITROS™ Immunodiagnostic Products Anti-HAV Total Reagent Pack	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1938	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-26-08-26-1525	Imager II Angiographic Catheters	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	Single-use devices
9	SA-24-08-26-1521	Centricity High Acuity Anesthesia (CHA A) and Centricity High Acuity Critical Care (CHA CC)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	Anaesthetic and respiratory devices
10	SA-26-08-26-1524	Automated Impella Controller (AIC)	ABIOMED Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	Active Implantable Devices
11	SA-26-08-26-1528	GEM PAKs for GEM Premier 5000 with iQM2® and GEM Premier 7000 with iQM3®	Instrumentation Laboratory SpA, a Werfen Company	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	In vitro diagnostic devices
12	SA-25-08-26-1522	MR systems with SW versions R5 & R11	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	Diagnostic and therapeutic radiation devices
13	SA-25-08-26-1523	BV Endura, BV Pulsera, BV Vectra, Veradius, and Zenition	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	Diagnostic and therapeutic radiation devices
14	SA-24-08-26-1520	BIOFIRE® FILMARRAY® TORCH System	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/1942	In vitro diagnostic devices