الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector
Surveillance and Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2644 **الرقم المرجعي للتقرير:**

Publish date: 25-Oct-26 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 18-Oct-26 من

To 24-Oct-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: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-19-10-26-1597	CNS-6200 Series Central Nurse Station	Nihon Kohden Corporation..	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.go	Hospital hardware
2	SA-19-10-26-1599	BU KWANG Crystal-Ject (Disposable syringe with needle)	BU KWANG MEDICAL INC.	humeidan and khowaiter co.	https://ade.sfda.go	Single-use devices
3	SA-18-10-26-1595	Philips Azurion systems	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
4	SA-18-10-26-1594	FreeStyle Libre 3 app	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-18-10-26-1596	Access HIV Ag/Ab Combo Calibrator	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.go	In vitro diagnostic devices
6	SA-18-10-26-1593	NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbits Company	https://ade.sfda.go	Anaesthetic and respiratory devices
7	SA-20-10-26-1600	BIOFIRE® FILMARRAY® Pneumonia Panel, BIOFIRE® FILMARRAY® Pneumonia plus Panel, and BIOFIRE® Joint Infection Panel	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/3013	In vitro diagnostic devices
8	SA-22-10-26-1604	i-STAT hs-TnI cartridge	Abbott Point of Care	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-20-10-26-1601	Dual IBP Adapter	Philips Medizin Systeme GmbH	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Reusable devices
10	SA-30-06-26-1449	LEONI plus / LEONI plus HFO / LEONI plus transport ventilators	Lowenstein Medical GmbH &Co.KG	Bio Standards	https://ade.sfda.go	Anaesthetic and respiratory devices
11	SA-18-10-26-1592	cobas c 703 Analytical Unit	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
12	SA-19-10-26-1598	TruSystem 7000 and TruSystem 7500	Baxter Healthcare	Baxter AG	https://ade.sfda.go	Hospital hardware