Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

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: WU2444 **الرقم المرجعي للتقرير:**

Publish date: 27-Oct-24 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **20-Oct-24** من

To **26-Oct-24** 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=CTLNDA7ARTRDHM

* 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: 14 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-22-10-24-636	3M™ V.A.C.® Ulta Therapy Unit	KCI USA Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
2	SA-23-10-24-643	AK 98 hemodialysis machines	Baxter Healthcare	Baxter AG	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
3	SA-23-10-24-642	Alinity ci-series System Control Module (SCM)	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.g	In vitro diagnostic devices
4	SA-22-10-24-639	Codman Surgical Patties	Integra LifeSciences Production Corporation	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
5	SA-22-10-24-635	GIF-1TH190 Gastrointestinal Videoscope	Olympus Europa SE & CO.KG..	Gulf Medical Co.	https://ade.sfda.g	Electro mechanical medical devices
6	SA-22-10-24-640	HScribe, RScribe, Welch Allyn Diagnostic Cardiology Suite, and Xscribe	Welch Allyn, Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ade.sfda.gov.sa/Fsca/Publish	Medical software
7	SA-23-10-24-641	Human Assayed Multi-Sera Level 3,	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.g	In vitro diagnostic devices
8	SA-17-10-24-632	Level 1 DI-50 Normothermic I.V. Fluid Administration Sets	Smiths Medical International Limited	almadar medical Est.	https://ade.sfda.g	Single-use devices
9	SA-20-10-24-633	Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	Baxter AG	https://ade.sfda.g	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-22-10-24-637	Minicap Extended Life PD Transfer Set with Twist Clamp	Baxter Healthcare	Baxter AG	https://ade.sfda.g	Single-use devices
11	SA-22-10-24-638	MiniMed Insulin Pumps	Medtronic MiniMed…	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices
12	SA-09-10-24-620	Philips OmniWire Pressure Guide Wire	VOLCANO CORPORATION	Ikar Establishment	https://ade.sfda.g	Single-use devices
13	SA-20-10-24-634	VIDAS Anti HBs TOTAL II 60T	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
14	SA-17-10-24-631	Vue PACS	Philips Medical Systems Nederland B.V.,	Bio Standards	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices