

Medical Devices Sector
Surveillance and Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

Report Reference: WU25 10
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التقرير الأسبوعي لإنذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 16-Feb-25 من
To 01-Mar-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:

- 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: 13 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-06-01-25-729	EDRAD Intego 200 PET Infusion Systems	Bayer Healthcare LLC..	Scientific & Medical Equipment House	https://ade.sfda.gov.sa/Fsca/PublishDetails/301	Electro mechanical medical devices
2	SA-20-02-25-792	Microstream™ Advance Neonatal-Infant and Adult-Pediatric Intubated CO2 Filter Line, Microstream™ Luer Adult-Pediatric Intubated CO2 Filter Line and Microstream™ Luer Adult-Pediatric Airway Adapter Sampling Line devices	Covidien LLC....	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/301	Single-use devices
3	SA-17-02-25-789	Abbott RealTime HIV-1 Amplification Reagent Kit and Alinity m HIV-1 AMP Kit	Abbott Molecular Division Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/62	In vitro diagnostic devices
4	SA-11-08-24-549	Aisys CS2, Avance CS2, Avance CS2 Pro, Aisys, Avance, Amingo, Aespire 100, Aespire View, Aespire 7900, and Aespire 7100 anesthesia devices equipped with the Auxiliary Common Gas Outlet (ACGO)	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/62	Anaesthetic and respiratory devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
5	SA-18-02-25-791	Anti-TPO ELISA Test System. An in vitro diagnostic medical device (IVD).	ORGENTEC Diagnostika GmbH...	Rustom Medical Est	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
6	SA-16-02-25-787	ASSURITY™ AND ENDURITY™ PACEMAKERS	Abbott..	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.gov.sa/Fsca/PublishD	Active Implantable Devices
7	SA-25-02-25-793	HAMILTON-C2/C3	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
8	SA-16-02-25-788	Intubation ORAL/NASAL Endotracheal Tube	Smiths Medical ASD, Inc.	almadar medical Est.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
9	SA-26-02-25-794	PF4 Enhanced® and PF4 IgG	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
10	SA-18-02-25-790	Revolution CT and Revolution Apex series CT systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
11	SA-13-02-25-786	Sedaconda Syringe	Sedana Medical AB	Techno-Orbits Establishment	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
12	SA-26-02-25-795	Shiley™ Adult Flexible Tracheostomy Tube with TaperGuard™ Cuff Reusable Inner Cannula	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/305	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
13	SA-10-02-25-781	Silvercel Hydro Alginate, Silvercel Non-Adherent, Tegaderm Alginate, ActivHeal Alginate, ActivHeal Aquafibre, ActivHeal Non-Adhesive Foam, ActivHeal Non Adhesive Tracheostomy, ActivHeal PHMB Foam Non-Adhesive, ActivHeal Raponice Ultra, Biatain Alginat	Advanced Medical Solutions Limited..	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishDetails/295	Single-use devices