

Safety Alerts Weekly Update

Report Reference: WU2445
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التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 27-Oct-24
To 02-Nov-24

من
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 إبذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إبذارات السلامة.
- لمعرفة تفاصيل الأجهزة والمستلزمات الطبية المتأثرة، الرجاء فتح رابط إذار السلامة:

No. of Safety Alerts: 8 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-29-10-24-651	- Aggressive Cutter, sterile Full Radius Resector, sterile - Aggr. Pro Line Shaver Blade, sterile - Round Burr, sterile - Aggressive Barrel Burr, sterile - Finish Barrel Burr, sterile - Semi Hooded Barrel Burr, sterile - Aggressive Barrel Burr, ste	KARL STORZ SE & Co. KG.	Karl Storz Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishDetails/167	Single-use devices
2	SA-27-10-24-646	Access Substrate	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/Publish	In vitro diagnostic devices
3	SA-29-10-24-650	bk3500, bk3000, bk5000 & bkActiv 2300 Ultrasound Devices with battery option	BK Medical Aps	GT Medical	https://ade.sfda.gov.sa/Fsca/Publish	Diagnostic and therapeutic radiation devices
4	SA-30-10-24-652	BRYCEMED FACE MASK	Xiantao Tongda Nonwoven Products Co Ltd	modern digital company	https://ade.sfda.gov.sa/Fsca/Publish	Single-use devices
5	SA-29-10-24-649	NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbits Company	https://ade.sfda.gov	Diagnostic and therapeutic radiation devices
6	SA-30-10-24-653	Safari Discovery Series Latex medical examination gloves	TG MEDICAL SDN. BHD.	Abdulrauf Ibrahim Batterjee & Bros. Company	https://ade.sfda.gov	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
7	SA-28-10-24-648	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 Raponicel Ultra, Biatain Alginate,	ADVANCED MEDICAL SOLUTIONS LTD..	Eyad I Alshedwy Comm Est	https://ade.sfda.gov.sa/Fsca/PublishDetails/161	Single-use devices
8	SA-28-10-24-647	Universal Remote Control	Getinge Sterilization AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/Publish	Electro mechanical medical devices