

Safety Alerts Weekly Update

Report Reference: WU2429
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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 07-Jul-24
To 13-Jul-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: 11 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-04-07-24-495	Alinity Alinity c Proteins Standardc Proteins Standard	Abbott Laboratories Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
2	SA-03-07-24-492	Arctic Sun 5000	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
3	SA-08-07-24-499	BLUselect Tracheostomy	Smiths Medical International Limited	almarad medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
4	SA-04-07-24-496	CALiaGold pierce Tube	Sentinel.CH.SpA.	Sysmex LLC One Person Co	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
5	SA-30-06-24-486	CPT Hip System Femoral Stem 12/14 Neck Taper	Zimmer Biomet	Zimmer Biomet Asel Alarabia	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
6	SA-07-07-24-498	Fassier-Duval Female Retriever	OrthoPediatrics Corp	ProMedEx	https://ncmdr.sfda.gov.sa/Secure/CA	Non-active implantable devices
7	SA-08-07-24-500	HeartStart Intrepid	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
8	SA-09-07-24-503	Medtronic NIM™ Standard Reinforced EMG Endotracheal Tube & NIM CONTACT™ Reinforced EMG Endotracheal Tube	Medtronic XOMED, Inc	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=211	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-26-06-24-480	MEGADYNE" MEGA SOFT" Dual Reusable Patient Return Electrode MEGADYNE" MEGA SOFT" Reusable Patient Return Electrode MEGADYNE" MEGA 2000" Patient Return Electrode	Megadyne Medical Products Inc.	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=21119	Reusable devices
10	SA-04-07-24-497	NIM Vital Nerve Monitoring System	Medtronic XOMED, Inc	Medtronic Saudi Arabia	https://ncmdr.sfda	Electro mechanical medical devices
11	SA-03-07-24-493	Precision Surgical Table PST 500 U	Baxter Healthcare.	Baxter AG	https://ncmdr.sfda	Electro mechanical medical devices