

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2638

الرقم المرجعي للتقرير:

Publish date: 13-Sep-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 06-Sep-26

من

To 12-Sep-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:

* مسؤولية ضابط الاتصال:

- 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.

- 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:



Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

No. of Safety Alerts: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-09-09-26-1549	Dexcom G7 iOS App	DexCom Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/1963	Medical software
2	SA-09-09-26-1550	Dexcom G7 App	DexCom Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/1964	Medical software
3	SA-06-09-26-1543	Liquid Urine Control - Level 2, Liquid Assayed Chemistry Control Premium Plus – Level 2, Liquid Assayed Chemistry Control Premium Plus – Level 3	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishDetails/1963	In vitro diagnostic devices
4	SA-07-09-26-1545	Artisan Link Pro and Artisan Link System	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/1964	In vitro diagnostic devices
5	SA-07-09-26-1546	NDI Passive Spheres	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/1964	Single-use devices
6	SA-07-09-26-1544	SDS Solution 10% (w/v), SDS Solution 20% (w/v) , 4X Laemmli Sample Buffer, XT Sample Buffer, Bio-Safe Coomassie Stain	Bio-Rad Laboratories, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/1964	In vitro diagnostic devices
7	SA-09-09-26-1548	PARENTE NC - PTCA BALLOON CATHETER	nabd Ilsnaat Company Medical	nabd Ilsnaat Company Medical	https://ade.sfda.gov.sa/Fsca/PublishDetails/1964	Single-use devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-09-09-26-1551	HemosIL AcuStar HIT-IgG (PF4-H)	Werfen..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishDetails/567	In vitro diagnostic devices
9	SA-06-04-26-1346	Sodium Bicarbonate	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ade.sfda.gov.sa/Fsca/PublishDetails/567	Single-use devices
10	SA-30-09-25-1073	CARESCAPE B450, CARESCAPE ONE, B1x5M/B1x5P VSP3.0, B1x5M/B1x5P VSP4.0 Patient Monitors and Portrait Vital Signs Monitor	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/567	Electro mechanical medical devices