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: WU2433 **الرقم المرجعي للتقرير:**

Publish date: 11-Aug-24 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **04-Aug-24** من

To **10-Aug-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=CTLNDA7ARTRDHMA

* 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: 10 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-05-08-24-545	Angiography system INFX-8000C and INFX-8000V	Canon Inc	Gulf Medical Co.	https://ade.sfda.go	Diagnostic and therapeutic radiation devices
2	SA-08-08-24-547	AZURION 7 M20	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
3	SA-04-08-24-541	IMMAGE Immunoglobulin M (IgM)	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.go	In vitro diagnostic devices
4	SA-28-07-24-537	IRISpec CA/CB/CC	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
5	SA-28-07-24-534	Liquid Assayed Chemistry Premium Plus Level 1	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.go	In vitro diagnostic devices
6	SA-04-08-24-542	Liquid Assayed Chemistry Premium Plus Level 2	Randox Laboratories Ltd.	Bio Standards	https://ade.sfda.go	In vitro diagnostic devices
7	SA-22-10-23-114	Monoclonal Mouse Anti-Human MSH2, Clone FE11 (Dako Omnis), Monoclonal Rabbit Anti-Human MSH6, Clone EP49 (Dako Omnis), and Monoclonal Rabbit Anti-Human PMS2, Clone EP51 (Dako Omnis).	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/50	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-01-08-24-539	Nasopharyngeal Airway and Thermovent 1200	Smiths Medical International Limited	almadar medical Est.	https://ade.sfda.go	Single-use devices
9	SA-07-08-24-546	Portex™ Blue Line Siliconised PVC Tracheotomy Tube	Smiths Medical International Limited	almadar medical Est.	https://ade.sfda.go	Single-use devices
10	SA-05-08-24-544	ZOLL Powerheart G5 AED, Semi-Automatic	Cardiac Science Corporation	Mohammed Binmahfouz Trading Est	https://ade.sfda.go	Electro mechanical medical devices