

Medical Devices Sector
Surveillance and Biometrics Executive Department

Safety Alerts Weekly Update

17-Dec-23

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 10-Dec-23 من
To 16-Dec-23 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=LK7JLRD397T7DFFR>



* 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 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 الطراز او الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Safety Alerts: 21 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-12-12-23-204	Assayed Urine Control Level 2	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
2	SA-10-12-23-194	BD Alaris™ System with Guardrails™ Suite MX	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA	Reusable devices
3	SA-06-12-23-190	BD Calibrite™ 3-Color Kit and BD® Stem Cell Enumeration Kit	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
4	SA-04-12-23-184	BrightView, BrightView X, BrightView XCT	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
5	SA-07-12-23-191	CALiaGold® Calibrator	Sentinel.CH.SpA	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
6	SA-12-12-23-203	Calibration Serum Level 3, Human Assayed Multi-Sera Level 2 and Level 3	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
7	SA-13-12-23-208	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
8	SA-05-12-23-188	INGENIO, VITALIO, and ADVANTIO pacemakers and INLIVEN, INTUA, and INVIVE cardiac resynchronization therapy pacemakers (CRT-Ps)	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=198	Active Implantable Devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-07-12-23-192	LIAISON® 25 OH Vitamin D TOTAL Assay, LIAISON® 25 OH Vitamin D TOTAL Assay 200	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
10	SA-12-12-23-206	MAQUET CARDIOSAVE Hybrid and MAQUET CARDIOSAVE Rescue	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
11	SA-10-12-23-195	neuromate system	Renishaw Mayfield	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	Medical software
12	SA-05-12-23-185	ORTHO VISION® Analyzer for BioVue when Processing ORTHO™ Sera Anti-Jkb Blood Grouping Reagent (Software 5.14.5 and below) ORTHO VISION® Max Analyzer for BioVue when Processing ORTHO™ Sera Anti-Jkb Blood Grouping Reagent (Software 5.14.5 and below)	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19827	In vitro diagnostic devices
13	SA-11-12-23-199	Philips Azurion System R1.0, R1.1, R1.2, R2.0, R2.1, and R2.2	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
14	SA-12-12-23-205	Proclaim™ XR SCS and Proclaim™ Elite SCS System, Proclaim™ DRG Neurostimulation System, Infinity™ DBS System	Abbott..	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=198	Active Implantable Devices
15	SA-10-12-23-193	Refer to the FSN	Karl Storz Endoscopy UK Ltd	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	Hospital hardware

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
16	SA-11-12-23-201	Sensis, Sensis Vibe Hemo, Sensis Vibe Combo	Siemens Healthcare GmbH	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA	Diagnostic and therapeutic radiation devices
17	SA-12-12-23-207	SOLTIVE Laser System	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA	Single-use devices
18	SA-27-11-23-175	Surdial X	Nipro Corporation.	Al-Faisaliah Medical System	https://ncmdr.sfda.gov.sa/Secure/CA	Electro mechanical medical devices
19	SA-10-12-23-197	VIDAS® CK-MB	bioMerieux Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA	In vitro diagnostic devices
20	SA-05-12-23-186	VITROS Immunodiagnostic Products Anti-HBs Reagent Pack VITROS Immunodiagnostic Products Anti-HBs Calibrators	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19828	In vitro diagnostic devices
21	SA-05-12-23-187	Zoom Programming System	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ncmdr.sfda.gov.sa/Secure/CA	Medical software