

Safety Alerts Weekly Update

Report Reference: WU2418
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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 21-Apr-24
To 27-Apr-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=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 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 إنذار السلامة:

No. of Safety Alerts: 13 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-21-04-24-369	BEYER Antrum Punch 615010 - Antrum Punch, 65°, 11 cm 615025 - Sphenoid Punch, 30°, 11 cm 648500 - Sphenoid Punch, 3.2 x 4 mm 648523 - Sphenoid Punch, 30°, 1.6 x 2 mm 662797 - Galea Spring Hook, 31 cm 723014 - Uvula Retractor Seite 2 von 4 7	KARL STORZ SE & Co. KG.	Karl Storz Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=21006	Non-active implantable devices
2	SA-22-04-24-374	Free T3 Reagent Pack Free T3 Calibrators	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
3	SA-22-04-24-378	High Flow Insufflation Unit	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/	Electro mechanical medical devices
4	SA-22-04-24-373	HistoCore Pegasus Devices	Leica Biosystems Newcastle	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
5	SA-17-04-24-364	Incisive CT/CT 3500/CT 5300 System	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
6	SA-19-04-24-368	IQon, iCT, Ingenuity, and Brilliance CT 64 systems	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	Diagnostic and therapeutic radiation devices
7	SA-21-04-24-370	leg holder	MAQUET Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/	Hospital hardware
8	SA-21-04-24-371	OLYMPUS Triangle Tip Electrosurgical Knives, Single Use Electrosurgical Knife	Olympus Corporation of the Americas .	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/	Ophthalmic and optical devices
9	SA-18-04-24-365	Portex™ Blue Line Siliconised PVC Tracheotomy Tube	Smiths Medical International Limited	almdar medical Est.	https://ncmdr.sfda.gov.sa/Secure/CA/	Single-use devices
10	SA-18-04-24-366	Quo-Lab A1C Test Kit / REF 0055 PocketChem™ Alc HbA1c Test Kit / REF 0130	EKF DIAGNOSTIC GmbH	GAMSCO (General Analysis for Medical Services Company)	https://ncmdr.sfda.gov.sa/Secure/CA/	In vitro diagnostic devices
11	SA-19-04-24-367	Rechargeable Deep Brain Stimulation (DBS) Implantable Pulse Generator (IPG) Resets VERCISE GENUS R16 IPG KIT VERCISE GENUS R32 IPG KIT	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=21004	Active Implantable Devices
12	SA-21-04-24-372	StealthStation S8 Application	Medtronic Navigation, Inc.	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/	Diagnostic and therapeutic radiation devices
13	SA-24-04-24-380	Synapse PACS	FUJIFILM Medical Systems	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/	Medical software