

Safety Alerts Weekly Update

التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2624

الرقم المرجعي للتقرير:

Publish date:

07-Jun-26

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 24-May-26

من

To 06-Jun-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 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:



Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

No. of Safety Alerts: 16 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-03-06-26-1414	SX-ELLA Stent Danis (Danis Stent), Danis Procedure Pack – Basic, Danis Procedure Pack	ELLA-CS, s.r.o.	janat al arab trading	https://ade.sfda.gov.sa/Fsca/PublishDetails/842	Non-active implantable devices
2	SA-24-05-26-1405	IntelliCuff	HAMILTON MEDICAL AG	Daleel Al Raeda Trading Est	https://ade.sfda.gov.sa/Fsca/PublishDetails/836	Anaesthetic and respiratory devices
3	SA-24-05-26-1406	Angiograph Control Syringe with Rotating Adaptor (RA) fitting in Kimal Procedure Pack	Kimal plc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishDetails/836	Single-use devices
4	SA-21-05-26-1402	Omnipod DASH® Insulin Management System	Insulet Corporation.	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishDetails/836	Electro mechanical medical devices
5	SA-31-05-26-1412	TU2000 TRYTABLE	MEDKONSULT medical technology s.r.o..	ATTIEH MEDICO LTD	https://ade.sfda.gov.sa/Fsca/PublishDetails/836	Diagnostic and therapeutic radiation devices
6	SA-28-05-26-1408	Harmony™ Delivery Catheter System	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/841	Non-active implantable devices
7	SA-31-05-26-1410	Inceptiv™/Intellis™ Pro INS Functionality- Model A71400 Stimulation RC Clinician Programmer Application	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishDetails/841	Active Implantable Devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-03-06-26-1416	Philips Avalon Fetal Monitor	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Hospital hardware
9	SA-02-06-26-1413	sleep.safe harmony	Fresenius Medical Care.	Fresenius Medical Care GmbH	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
10	SA-04-06-26-1417	DLP™ One-Piece Pediatric Arterial Cannula & Bio-Medicus™ Adult Cannula Kit	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
11	SA-21-05-26-1404	O-arm™ O2 Imaging System	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
12	SA-31-05-26-1409	GSP Neonatal GALT kit	Wallac Oy	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
13	SA-24-05-26-1407	Kimal procedure packs	Kimal plc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
14	SA-03-06-26-1415	TG medical Latex Examination Gloves Powder Free	Great Glove (Thailand) Co., Ltd	Bassam Trading Company Ltd	https://ade.sfda.gov	Single-use devices
15	SA-21-05-26-1403	Octopus™ Tissue Stabilizer	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
16	SA-21-03-24-339	All BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro devices	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/142	Anaesthetic and respiratory devices