

Safety Alerts Weekly Update

التقرير الأسبوعي لإنذارات السلامة

Report Reference: WU2535

الرقم المرجعي للتقرير:

Publish date: 24-Aug-25

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 17-Aug-25

من

To 23-Aug-25

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=4MT7LEJ3DFP7H8LJ>



* 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:

No. of Safety Alerts: 12 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-14-08-25-1003	Medin-NC3	medin Medical Innovations GmbH	Anfas Arabia Trading Company	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
2	SA-17-08-25-1013	PhD Hemostasis Valve™	Merit Medical Systems Inc....	Medical Regulations Gate	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
3	SA-19-08-25-1015	DLP Left Heart Vent Catheter. Malleable body and vented connector.	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
4	SA-10-08-25-993	t:slim X2 Insulin Pump	Tandem Diabetes Care, Inc	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices
5	SA-17-08-25-1006	Multiple MRI systems	Siemens Medical Solutions	Siemens Medical Solutions	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
6	SA-15-08-25-1005	MediHoney® Wound and Burn Products	Derma Sciences, Inc	TABASSOM TRADING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
7	SA-14-08-25-1004	BeneVision N1 Patient Monitor	Shenzhen Mindray Bio-Medical Electronics Co., Ltd...	Bio Standards	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
8	SA-17-08-25-1011	ROTEM® sigma complete. ROTEM® sigma complete + hep.	Werfen..	ABDULLA FOUAD HOLDING COMPANY	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
9	SA-19-08-25-1014	ELAN 4 FIXED DURAGUARD	Aesculap	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices

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10	SA-19-08-25-1016	Heartstring III Proximal Seal System	MAQUET Cardiovascular LLC.	Medical Elements	https://ade.sfda.gov.sa/Fsca/PublishDetails/507	Single-use devices
11	SA-17-08-25-1012	StentFlex Over-the-Wire Embolectomy Catheter, Pruitt Occlusion Catheter & Pruitt Irrigation Occlusion Catheter	LeMaitre Vascular, Inc.	Almarfa Medical	https://ade.sfda.gov.sa/Fsca/PublishDetails/507	Single-use devices
12	SA-25-10-23-118	Achieva 1.5T, Achieva 1.5T Conversion, Ingenia 1.5T CX, Intera 1.5T, Intera 1.5T Power/Pulsar, SmartPath to dStream for 1.5T	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishDetails/85	Diagnostic and therapeutic radiation devices