الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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: WU2647 **الرقم المرجعي للتقرير:**

Publish date: 15-Nov-26 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **08-Nov-26** من

To **14-Nov-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:

- 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: 14 **عدد إنذارات السلامة**

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-06-11-26-1634	Rotaflow Console	MAQUET Inc	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
2	SA-12-11-26-1646	Nova StatStrip® Ketone Test Strips	Nova Biomedical Corporation.	SAUDI INTERNATIONAL TRADING COMPANY LTD	https://ade.sfda.go	In vitro diagnostic devices
3	SA-08-11-26-1638	SynchroMed™ A820 myPTM Application Software	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.go	Medical software
4	SA-12-11-26-1647	Humidifier systems of the Stephanie and Sophie ventilators with P7 patient unit	Fritz Stephan GmbH.	Al Khateeb United Trading Est.	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices
5	SA-09-11-26-1639	Brainlab Navigation Software Cranial EM	Brainlab AG...	Elite Smart Solutions	https://ade.sfda.go	Medical software
6	SA-04-11-26-1632	DxC 500i Clinical Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
7	SA-04-11-26-1631	DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.go	In vitro diagnostic devices
8	SA-08-11-26-1637	Atellica CH and CI Analyzers	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
9	SA-06-11-26-1635	GETINGE Solsus 66	Getinge Disinfection AB	Gulf Medical Co.	https://ade.sfda.gov.sa/Fsca/PublishD	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
10	SA-08-11-26-1636	Atellica CH Analyzer and Atellica CI Analyzer	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	https://ade.sfda.go	In vitro diagnostic devices
11	SA-09-11-26-1640	BD Connecta™ Stopcock	BD Switzerland Sarl	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
12	SA-10-11-26-1643	Vercise™ Deep Brain Stimulation Systems	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	https://ade.sfda.go	Active Implantable Devices
13	SA-11-11-26-1645	Infinity™ Ammonia Reagent for Beckman Coulter AU Chemistry Analyzers	Thermo Fisher Scientific Inc...	Beckman Coulter Saudi Arabia Co Ltd	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices
14	SA-28-10-26-1619	COULTER DxH Diluent	Beckman Coulter....	DHR Diagnostics Arabia Limited	https://ade.sfda.gov.sa/Fsca/PublishD	In vitro diagnostic devices