Kingdom of Saudi Arabia
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

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: WU2446 **الرقم المرجعي للتقرير:**

Publish date: 10-Nov-24 **تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From **03-Nov-24** من

To **09-Nov-24** 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 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: 9 **عدد إنذارات السلامة**

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-04-11-24-659	- Argus 717V - Argus 718V	Codan Argus AG	Al-Jeel Medical & Trading Co. LTD	https://ade.sfda.go	Electro mechanical medical devices
2	SA-04-11-24-656	BD BACTEC™ Blood Culture System BD Phoenix™ M50 Automated Microbiology System BD MAX™ System BD COR™ System BD EpiCenter™ Microbiology Data Management System BD Synapsys™ Informatics Solution	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ade.sfda.gov.sa/Fsca/PublishDetails/172	In vitro diagnostic devices
3	SA-06-11-24-663	Becker and Exacta external drainage and monitoring systems (EDMS).	Medtronic Inc.	Medtronic Saudi Arabia	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
4	SA-07-11-24-665	Discovery, Optima, Revolution series CT systems, and certain operator console upgrades	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
5	SA-31-12-23-235	EVair and EVair 03 (Jun-Air)	Datex - Ohmeda Inc	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Anaesthetic and respiratory devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
6	SA-13-10-24-626	Infusomat Space Line	B Braun Medical Inc	Medical supplies & Services Co.Ltd Mediserv	https://ade.sfda.gov.sa/Fsca/PublishD	Single-use devices
7	SA-04-11-24-658	Philips MR system breast coils	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
8	SA-03-11-24-655	Proteus XR/a	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices
9	SA-03-11-24-654	SIGNA Architect, Discovery MR750w 3.0T, and SIGNA PET/MR systems	GE Healthcare	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD	Diagnostic and therapeutic radiation devices