

### Safety Alerts Weekly Update

### التقرير الأسبوعي لإبذارات السلامة

Report Reference:

WU2427

الرقم المرجعي للتقرير:

Publish date:

30-Jun-24

تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 23-Jun-24

من

To 29-Jun-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 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: 16 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-24-06-24-467	- Leoni plus HFO - Leoni plus Transport	Lowenstein Medical GmbH &Co.KG	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices
2	SA-24-06-24-465	A subset of Medtronic LINQ II™ Insertable Cardiac Monitoring Systems (LNQ22)	Medtronic Inc.	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Active Implantable Devices
3	SA-25-06-24-473	Alinity hq Analyzer.	Abbott	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
4	SA-25-06-24-475	BeneHeart C2	Shenzhen Mindray Bio-Medical Electronics Co., Ltd...	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
5	SA-13-06-24-460	BeneHeart D1 Automated External Defibrillator	Shenzhen Mindray Bio-Medical Electronics Co., Ltd...	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
6	SA-21-03-24-339	BiPAP A30, BiPAP A30 EFL, BiPAP A30 Hybrid, BiPAP A40, BiPAP A40 EFL, BiPAP A40 Pro	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices
7	SA-24-06-24-468	BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices
8	SA-23-06-24-463	Cholesterol	Thermo Fisher Scientific Oy	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-24-06-24-466	CUSA Excel C2600 23kHz Straight Handpiece	Integra LifeSciences	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
10	SA-25-06-24-470	ESG-410 Electrosurgical Generator	Olympus Europa SE & CO.KG..	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
11	SA-20-06-24-462	Idylla EGFR Mutation Test.	Biocartis NV.	Advance Test Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	In vitro diagnostic devices
12	SA-25-06-24-477	MR systems	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Diagnostic and therapeutic radiation devices
13	SA-21-03-24-338	OmniLab Advanced + (OLA+)	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices
14	SA-25-06-24-471	SPACEPLUS INFUSOMAT	B. Braun Melsungen AG.	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Electro mechanical medical devices
15	SA-25-06-24-472	Trevo Retrievers/Microcatheters, FlowGate2, Distal Access Catheter (DAC) and Synchro	Stryker Neurovascular	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Single-use devices
16	SA-14-06-24-461	Trilogy Evo, Trilogy Evo O2, and Trilogy EV300	Respironics Inc	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	Anaesthetic and respiratory devices