

**Safety Alerts Weekly Update**

**التقرير الأسبوعي لإنذارات السلامة**

**Report Reference:** WU2532

**الرقم المرجعي للتقرير:**

**Publish date:** 03-Aug-25

**تاريخ النشر:**

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

فيما يلي التقرير الأسبوعي لإنذارات السلامة للفترة:

From 27-Jul-25

من

To 02-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: 9 عدد إنذارات السلامة

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
1	SA-30-07-25-981	RELIANCE ePTFE defibrillation	Boston Scientific Corp..	Boston Scientific Gulf for trading LLC	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Active Implantable Devices
2	SA-27-07-25-977	ESG-410 Electrosurgical Generator	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Reusable devices
3	SA-24-07-25-973	Celsite® Babyport	B. Braun Melsungen	ProMedEx	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Single-use devices
4	SA-27-07-25-978	DNA LoBind® Tubes 1.5mL, 250 Tubes	EPPENDORF AG,	ABDULLA FOUAD HOLDING COMPANY	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices
5	SA-27-07-25-976	PrisMax Systems and TherMax Blood Warmer Units	Vantive Health GmbH	Baxter AG	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices
6	SA-27-07-25-975	BD Alaris neXus GP Volumetric pumps	BD Switzerland Sarl	Becton Dickinson B.V.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Healthcare facility products and adaptations
7	SA-28-07-25-980	Enterprise Archive	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Medical software
8	SA-07-03-25-805	Vasoview Hemopro 2 (w/Vasoshield) Endoscopic Vessel Harvesting System	MAQUET Cardiopulmonary GmbH	Medical Elements	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	Electro mechanical medical devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
9	SA-28-07-25-979	FilmArray Pneumonia Panel Plus (Pneumoplus), FilmArray Pneumonia Panel (Pneumo)	BioFire Diagnostics Inc	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>	In vitro diagnostic devices