

### Safety Alerts Weekly Update

Report Reference: WU2430  
Publish date: 21-Jul-24

### التقرير الأسبوعي لإبذارات السلامة

الرقم المرجعي للتقرير:  
تاريخ النشر:

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

فيما يلي التقرير الأسبوعي لإبذارات السلامة للفترة:

From 14-Jul-24  
To 20-Jul-24

من  
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=CTLNDA7ARTRDHM>



\* 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 إذار 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-11-07-24-506	All products containing the component vacuum-tight reservoir (VHK 71000)	MAQUET Cardiopulmonary GmbH	Medical Elements	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Single-use devices
2	SA-04-07-24-494	Braun Thermoscan PRO 6000	Welch Allyn, Inc	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Electro mechanical medical devices
3	SA-11-07-24-507	DEFIGARD Touch7	Schiller AG	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Electro mechanical medical devices
4	SA-10-07-24-505	DLP™ Single Stage Venous Cannulae with right angle metal tip	Medtronic Inc.	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	Single-use devices
5	SA-15-07-24-511	Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds)	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ade.sfda.gov.sa/Fsca/Publish/Details/18">https://ade.sfda.gov.sa/Fsca/Publish/Details/18</a>	Active Implantable Devices
6	SA-15-07-24-512	Medtronic CareLink 2090 Programmer Autonomous Cursors	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Medical software
7	SA-15-07-24-510	Philips Azurion System R1.x	Philips Medical Systems Nederland B.V.	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Diagnostic and therapeutic radiation devices

Safety Alert No.	NCMDR Ref.	Medical Device	Manufacturer	Authorized Representative /Importer	Link	Medical Device Category
8	SA-17-07-24-515	ProCuity	Stryker	Al-Jeel Medical & Trading Co. LTD	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Hospital hardware
9	SA-14-07-24-508	Proteus XR/a Systems	GE Healthcare	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Diagnostic and therapeutic radiation devices
10	SA-30-06-24-485	Soltive SuperPulsed Laser System Wireless Footswitch TFL-AFSWL for Soltive Models: Pro TFL-SLS and Premium TFL-PLS	Olympus Corporation of the Americas .	Gulf Medical Co.	<a href="https://ade.sfda.gov.sa/Fsca/Publish/Details/19">https://ade.sfda.gov.sa/Fsca/Publish/Details/19</a>	Diagnostic and therapeutic radiation devices
11	SA-06-03-24-316	Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	Anaesthetic and respiratory devices
12	SA-15-07-24-509	VITROS XT Chemistry Products ALB-TP Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>	In vitro diagnostic devices