

Kingdom of Saudi Arabia
Saudi Food & Drug Authority



المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمستلزمات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Alerts Weekly Update

20-Aug-23

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

مرفق فيما يلي التقرير الأسبوعي لإذارات السلامة للفترة:

From 13-Aug-23 من
To 19-Aug-23 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمناثرة بها المملكة والتي جاري متابعتها مع الممثلين المعتمدين لإتمام تنفيذ الإجراءات التصحيحية.

* Role of contact officer:

* مسؤولية ضابط الاتصال:

* Kindly respond to the weekly report in both cases either you are affected or not affected.

* نأمل الرد على التقرير الأسبوعي في حالتي التأثر أو عدم التأثر.

- 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

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إذارات السلامة.
- التواصل مع الممثل المعتمد للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إذارات السلامة.

Name of Healthcare Facility:

اسم مقدم الرعاية الصحية:

Date:

التاريخ:

Facility affected by any device/product in this report:

يوجد أجهزة/مستلزمات متأثرة في المنشأة ضمن القائمة:

Yes

نعم

No

لا

- The yellow highlights indicates that medical devices subject to removal action.
- To identify the affected serial numbers/lots, please open the link.

- الإجراءات المظللة بالأصفر تشير إلى إجراء سحب الجهاز الطبي.
- لمعرفة الطراز أو الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Safety Alerts: 10 عدد إنذارات السلامة

| Medical Device | Manufacturer | Authorized Representative /Importer | Link | Affected Yes/No |
|----------------|--------------|-------------------------------------|------|-----------------|
|----------------|--------------|-------------------------------------|------|-----------------|

Active Implantable Devices

| | | | | |
|---------------------------------------|----------|-----------------------------------|---|--|
| HeartMate Touch™ Communication System | Abbott.. | Al-Jeel Medical & Trading Co. LTD | https://ncmdr.sfda.gov.sa/Secure/CA/ | |
|---------------------------------------|----------|-----------------------------------|---|--|

Diagnostic and therapeutic radiation devices

| | | | | |
|--------------------------------|-------------------------|--------------------------------------|---|--|
| Azurion and Allura Xper series | Philips Medical Systems | Philips Healthcare Saudi Arabia Ltd. | https://ncmdr.sfda.gov.sa/Secure/CA/ | |
|--------------------------------|-------------------------|--------------------------------------|---|--|

Electro mechanical medical devices

| | | | | |
|--|---------|-----------------------------------|---|--|
| Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP) | Getinge | Al-Jeel Medical & Trading Co. LTD | https://ncmdr.sfda.gov.sa/Secure/CA/ | |
|--|---------|-----------------------------------|---|--|

In vitro diagnostic devices

| | | | | |
|---|--|-------------------------------|---|--|
| ACL TOP SW 6.4.0. An in vitro diagnostic medical device (IVD) | Instrumentation Laboratory SpA, a Werfen Company | ABDULLA FOUAD HOLDING COMPANY | https://ncmdr.sfda.gov.sa/Secure/CA/ | |
| Diacon 3 hematology control ((Low) 6x, (Normal), (High) 6) | Diatron MI Plc. | Techno Orbits Company | https://ncmdr.sfda.gov.sa/Secure/CA/ | |

Medical software

| | | | | |
|-----------------------------|-----------------------|------------------|---|--|
| Zvu® Functional GI Software | Diversatek Healthcare | Gulf Medical Co. | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe | |
|-----------------------------|-----------------------|------------------|---|--|

Non-active implantable devices

| | | | | |
|--|--------------------------|--|---|--|
| Guider Softip™ 40XF and Guider Softip™ MPXF Guide Catheter | Boston Scientific Corp.. | Boston Scientific Gulf for trading LLC | https://ncmdr.sfda.gov.sa/Secure/CA/ | |
| Trifecta Valve and Trifecta Valve with Glide Technology | St. Jude Medical Inc., | Medical Regulations Gate | https://ncmdr.sfda.gov.sa/Secure/CA/ | |

Reusable devices

| Medical Device | Manufacturer | Authorized Representative /Importer | Link | Affected Yes/No |
|---|--------------|--|---|-----------------|
| PDS TM II (polydioxanone) Suture PDSTM Plus Antibacterial (polydioxanone) Suture | Ethicon Inc. | Johnson & Johnson Medical Saudi Arabia Limited | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx | |

Single-use devices

| | | | | |
|---------------|-----------------------------|-------------------|---|--|
| Gore tips set | W.L. Gore & Associates Inc. | Med Surg Supplies | https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx | |
|---------------|-----------------------------|-------------------|---|--|