

# Kingdom of Saudi Arabia Saudi Food & Drug Authority



# المملكة العربية السعودية الهيئة العامة للغذاء والدواء

Medical Devices Sector  
Surveillance Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية  
الإدارة التنفيذية للرقابة والقياسات الحيوية

## FSCA Weekly Update

04-Dec-22

Attached below is the weekly report of Field Safety Corrective Actions (FSCAs) for the period:

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية لإندارات السلامة للفترة:

From 27-Nov-22 من  
To 03-Dec-22 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.

\* 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 healthcare facility and Ensuring 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 FSCA

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

Hospital name:

اسم المستشفى:

Date:

التاريخ:

Hospital affected by any device/product in this report:

يوجد أجهزة/منتجات متأثرة بالمستشفى 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 او الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Field Safety Corrective Actions (FSCA): 13 عدد الإجراءات التصحيحية لإنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Active Implantable Devices

HeartWare™ Ventricular Assist Device (HVAD) System	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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### Anaesthetic and respiratory devices

Amara View Minimal Contact Full-Face Mask, DreamWear Full Face Mask, DreamWisp Nasal Mask with Over the Nose Cushion, Wisp Nasal Masks and Wisp Youth Nasal Masks, Therapy Mask 3100 NC/SP	Philips Respironics California	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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Polaris Multimedia	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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### Electro mechanical medical devices

KBM Digital Blood Pressure Monitor	Tanaka Sangyo Co., Ltd.	Noorwali Medical Store Co Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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Surgical Microscopes : M530 OHX, PROvido, Proveo 8	Leica Microsystems Inc.	Al-Faisaliah Medical System	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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### In vitro diagnostic devices

Accelerate PhenoTest BC kit	Accelerate Diagnostics Inc	Private Healthcare Establishment	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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Specific Protein Control Level 1-3	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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VIDAS® PC software	bioMerieux Inc	Jeel Medical & Trading Co. L	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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### Medical software

Guardian App	Medtronic MiniMed...	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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Oncentra Brachy	Nucletron bv	Medical regulations gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=17350</a>	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Syngo.via with VB20, VB30, VB40, VB60 and VB70 software	SIEMENS	Siemens Medical Solutions	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	

### Single-use devices

Revaclear 300 dialyzer.	AMBRO RENAL PRODUCTS IN	Baxter AG	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
Vliwaktiv Absorbent activated charcoal dressing	Lohmann & Rauscher	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	