

# 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

27-Dec-20

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 20-Dec-20 من  
To 26-Dec-20 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 أو الأرقام التسلسلية المتأثرة بالإجراء التصحيحي، يرجى فتح الرابط.

No. of Field Safety Corrective Actions (FSCA):

11

عدد الإجراءات التصحيحية لإنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Diagnostic and therapeutic radiation devices

Revolution Apex, Revolution CT with Apex Edition, Revolution CT, and Revolution CT ES Systems.	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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### Electro mechanical medical devices

A710 Intellis Clinician Programmer Application .	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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### Healthcare facility products and adaptations

Getinge Washer Disinfector CM320 ,	Getinge Disinfection AB	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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### Hospital hardware

Reliance Vision Single-Chamber Washer/Disinfector	STERIS Corporation..	Al-Jeel Medical & Trading Co. LTD	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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### In vitro diagnostic devices

9180 Electrolyte Analyzer ,	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Ltd	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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Ortho BioVue System Cassette products	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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ORTHO VISION Analyser for ORTHO BioVue Cassettes & Max Analyser for ORTHO BioVue Cassettes	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx</a>	
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VITROS® Chemistry Products TBIL Slides, BuBc Slides and VITROS® XT Chemistry Products TBIL-ALKP Slides	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=1548">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=1548</a>	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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### Non-active implantable devices

APEX HOLE ELIMINATOR (HE) USED WITH PINNACLE CUP	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
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### Single-use devices

BD Syringes and Needles	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15478">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15478</a>	
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-Pediatric Venous Hardshell Cardiotomy Reservoir - Combination of Pediatric Venous Hardshell Cardiotomy Reservoir with QUADROX-i Pediatric Oxygenator	MAQUET Cardiopulmonary GmbH	Medical Elements	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15478">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15478</a>	
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