



Medical Devices Sector  
Surveillance Biometrics Excutive Department

قطاع الأجهزة والمنتجات الطبية  
الإدارة التنفيذية للرقابة والقياسات الحيوية

## FSCA Weekly Update

29-Dec-19

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

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية للسلامة  
الميدانية للفترة:

From 22-Dec-19 من  
To 28-Dec-19 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  
للسلامة الميدانية

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): 12 عدد الإجراءات التصحيحية للسلامة الميدانية:

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

Velara X-ray generator used with Philips Allura Xper system, the Integris system, the MultiDiagnost Eleva system and OmniDiagnost system ,	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
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### Electro mechanical medical devices

Giraffe Blue Spot PT Lite Phototherapy Systems	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
Lullaby Warmer ,	Datex - Ohmeda Inc	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	

### Healthcare facility products and adaptations

Cracked coating fork on VOLISTA light	MAQUET Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
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### Hospital hardware

ANIOSYME DD1	ANIOS LABORATOIRES	Spectromed	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
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### In vitro diagnostic devices

Alinity hq Analyzer ,	Abbott	supplies & Services Co.Ltd M	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
Atellica IM NT-proBNP (PBNP) 100 Test Kit and 500 Test Kit	Siemens Healthcare Diagnostics Inc	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
FTD CE-IVD kits	ack Diagnostics Luxembourg	Integrated Gulfbiosystems	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
Idylla ctNRAS-BRAF Mutation Test	Biocartis NV.	Advance Test Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	

### Non-active implantable devices

Compress, Mini Compress	Zimmer, INC....	Medical Regulations Gate	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15013</a>	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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**Reusable devices**

Hanaulux sterilizable handle hub ,	MAQUET Inc	Gulf Medical Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
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**Single-use devices**

Polysorb™ braided and Biosyn™ monofilament absorbable sutures	Medtronic SA	Medtronic Saudi Arabia	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/">https://ncmdr.sfda.gov.sa/Secure/CA/</a>	
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