

# 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

08-Aug-21

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

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية لإبذارات السلامة للفترة:

From 01-Aug-21 من  
To 07-Aug-21 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 لإبذارات 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):

15

عدد الإجراءات التصحيحية لإنذارات السلامة

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

EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) EMBLEM™ S-ICD Subcutaneous Electrode (Model 3501)	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
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### Anaesthetic and respiratory devices

Datex-Ohmeda Anesthesia Machines	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
Zeus Infinity Empowered	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	

### Assistive products for persons with disability

Zippie Voyage	Sunrise Medical	Al-Enayah Company	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
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### Diagnostic and therapeutic radiation devices

Philips EPIQ & Affiniti Ultrasound Systems..	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
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### Electro mechanical medical devices

Root NIBPT devices	Masimo Corporation	Masimo International SARL	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
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### In vitro diagnostic devices

Accu-Chek® Aviva 50 Accu-Chek® Aviva 100	Roche Diabetes Care GmbH	FAROUK, MAAMOUN TAMER & COMPANY	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
Accu-Chek® Inform II test strips	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	
ADVIA Chemistry XPT System,,	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15787</a>	

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
EnVision FLEX Hematoxylin Link	Agilent Technologies, Inc.	Dar Al-Zahrawi Medical Co. LLC	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	

### Non-active implantable devices

GORE PROPATEN Vascular Graft configured for Pediatric Shunt	W.L. Gore & Associates Inc.	Med Surg Supplies	<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 SmartSite™ Needle Free Valve	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
Prismaflex Sets..	Baxter Corp Canada	Baxter AG	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
Steelex STE set, Steelex monofilar and packs	B Braun Surgical SA	Gulf Medical Co.	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
TheraSphere Administration Sets	Biocompatibles Ltd	Arabian Trade House Est.	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	