

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

13-Jun-21

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

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية لإذارات السلامة للفترة:

From 06-Jun-21 من
To 12-Jun-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 لإذارات 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):

13

عدد الإجراءات التصحيحية لإنذارات السلامة

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

Cardiac Resynchronization Therapy pacemakers (VISIONIST™, □,) and pacemakers (ACCOLADE™, PROPONENT™ and ESSENTIO™)	Boston Scientific Cardiac Rhythm Management Group	FAROUK, MAAMOUN TAMER & COMPANY	https://fsca.swissmedic.ch/mep/api/publications/Vk_20180911_13/documents/10	
HeartWare Ventricular Assist Device (HVAD) System	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda	
INGENIO, VITALIO, and ADVANTIO pacemakers and INLIVEN, INTUA, and INVIVE cardiac resynchronization therapy pacemakers (CRT-Ps)	Boston Scientific Corporation	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=156	

Diagnostic and therapeutic radiation devices

CARESCAPE PDM with Masimo SET technology	GE Healthcare	GE Healthcare	https://ncmdr.sfda	
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Electro mechanical medical devices

HeartStart Intrepid Monitor/Defibrillator	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda	
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In vitro diagnostic devices

Atellica UAS 800 Urine Sediment Analyser and Atellica 1500 Automated Urinalysis System	Siemens Healthcare Diagnostics	Abdulrauf Ibrahim Batterjee & Bros. Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Dimension® EXL™ integrated chemistry system, LOCI Module LOCI High-Sensitivity Troponin I (TNIH) Flex® reagent cartridge	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	
i-STAT CG8+ cartridges i-STAT EG7+ cartridges	Abbott Point of Care	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	
VIDAS® Anti-HBs Total II	bioMerieux Inc	Jeel Medical & Trading Co. L	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	

Ophthalmic and optical devices

Buffalo Filter LaparoVue Visibility System	ConMed Corporation...	Cure Development International Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	
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Single-use devices

Medical devices within shelf life that were sterilized at Steril Milano.	Delta Med spa	Gebab Najed Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	
MEDIK PRIME Natural Latex Gloves	Salalah Medical Supplies Mfg. Co.	Omuk Altadamen Medical Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	
THORAMETRIX drainage system	Biometrix SRO	Sarabeel Commercial Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15701	