

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

07-Mar-21

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 28-Feb-21 من
To 06-Mar-21 إلى

which affect Saudi Arabia and being followed up with the authorised representatives to accomplish the required action.

والمناثرة 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 متاثرة 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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Anaesthetic and respiratory devices

fabian HFO and fabian +nCPAP evolution ventilators	Acutronic Medical Systems AG..	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
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Electro mechanical medical devices

Duodenoscopes and Single-Use Distal Covers	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
Duodenoscopes and Single-Use Distal Covers	Olympus	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
FRED Easy, FRED Easy Skity	Schiller AG	supplies & Services Co.Ltd M	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
LIFEPAK CR2 Defibrillators	Stryker	Jeel Medical & Trading Co. L	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
Root Monitoring Systems	Masimo Corporation	Masimo International SARL	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	

In vitro diagnostic devices

All AQT90 FLEX analyzers with serial numbers of 393-838R0564 onwards and all E3800 spare part CPU units, 910-415.(IVD)	Radiometer Medical	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
BOND Ready-to-Use Primary Antibody CD19 (BT51E), Novocastra Liquid Mouse Monoclonal Antibody CD19	Leica Biosystems Newcastle	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
ClinCal Whole Blood Calibrator Immunosuppressants	Recipe Chemicals & Instruments GMBH	NAIZAK GLOBAL ENGINEERING LAB SYSTEMS	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
DiaClon Anti-M/N* and DiaClon Anti-N	DiaMed GmbH.	ABDULREHMAN AL GOSAIBI GTB	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	
Immucor GTI Diagnostics LIFECODES MATCH IT!	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=155	

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
VITROS Chemistry Products Calibrator Kit 4 Performance Update for VITROS Chemistry Product TIBC Kit	Ortho-Clinical Diagnostics	Samir Photographic Supplies Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx	

Single-use devices

Sterile Single Use Syringe 60ml Luer lock without needle	Saudi Mais for Medical Products	Saudi Mais Co. For Medical Products	https://ncmdr.sfda.gov.sa/Secure/CA/	
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