

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

01-Aug-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 11-Jul-21 من
To 31-Jul-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):

24

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	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=1575 3	
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Diagnostic and therapeutic radiation devices

CombiDiagnost R90	Philips Healthcare	Philips Healthcare Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Ingenia 1.5T, Ingenia 1.5T Evolution, Ingenia 3.0T, Ingenia Elition X Magnetic Resonance System	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
Philips EPIQ Ultrasound Systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

Electro mechanical medical devices

Root Monitoring Systems	Masimo Corporation	Masimo International SARL	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
TFL-PLS SOLTIVE Premium SuperPulsed Laser System	Gyrus ACMI	Salehiya Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

In vitro diagnostic devices

Accu-Chek® Aviva 50 Accu-Chek® Aviva 100	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Alinity ci-series System Control Module (SCM)	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Alinity s System.m	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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=157	
Copper CU2340 R1a Buffer	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
ID-Antigen profile II	DiaMed GmbH.	DULREHMAN AL GOSAIBI G	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
Rheumatoid Factor reagent	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
Set ID- DiaPanel Plus 6	DiaMed GmbH.	DULREHMAN AL GOSAIBI G	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	

Laboratory equipment

Alinity ci-series	Data Innovations.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
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Non-active implantable devices

ALGAFLEX lines	Perouse Medical..	Ameesa Medical Instruments	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
BIB / Orbera / Orbera365 Intra-gastric Balloon Systems	Apollo Endosurgery Inc.	Al-Nozha Medical Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
OXACILLIN 1UG ANTIMICROBIAL DISC	Abtek biologicals LTD	watin biolife advanced diagnostics mfr	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	

Ophthalmic and optical devices

Sunglasses JK BI 1110	ENZHOUBIAO YI OPTICAL LTD	Al Jamil Optical Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
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Single-use devices

Damad-set Dressing pack; Oral Care Kit	The National Medical Products Co. Ltd. (Damad)	The National Medical Products Co. Ltd. (Damad)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
HARMONIC HD 1000i Shears	Johnson & Johnson Medical Gr	Johnson Medical Saudi Arab	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology, , ,	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
RUSCHELIT Super Safety Clear Tracheal Tube	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	
Supraflow® supra-pubic drainage set	Coloplast	janat al arab trading	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=157	