

Medical Devices Sector
Surveillance Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

FSCA Weekly Update

11-Jun-23

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 **04-Jun-23** من
To **10-Jun-23** إلى

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

والتأثرة 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 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): 19 عدد الإجراءات التصحيحية لإنذارات السلامة

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Anaesthetic and respiratory devices

NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbits Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	Techno Orbits Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
Oxylog 3000 plus	Draeger Medical Systems Inc	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
The Timeter Sure Grip Flowmeter	Allied Healthcare Products Inc.	United Medical Supplies	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	

Assistive products for persons with disability

Treatment chairs 500 XLE	FSK-International OSYS Gmb	First Gulf Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
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Dental devices

Articulating Paper	N/A.	AL RAZI MEDICAL SUPPLIES	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
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Diagnostic and therapeutic radiation devices

Azurion and Allura Xper series	Philips Medical Systems	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
Ingenia Elition, SmartPath to Ingenia Elition X, MR 7700 and 'Upgrade to MR 7700' MR systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
I-sensor/H2	Podpecker Medical Instrumenter	AL RAZI MEDICAL SUPPLIES	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
OmniTom and OmniTom Elite	Neurologica Corp.,	Min Medical Instruments Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
Shimadzu X-Ray system - X-Ray tube support, ceiling mounted CH-200/CH-200M	Shimadzu Corporation..	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	

Electro mechanical medical devices

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
NO-Therapy device NO-A (in combination with ventilator Leoni Plus)	EKU Elektronik GmbH.	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	
NO-Therapy device NO-A (in combination with ventilators Servo-n and Servo-u)	EKU Elektronik GmbH.	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	
NO-Therapy device NO-A (in combination with ventilators Servo-n and Servo-u)	EKU Elektronik GmbH.	Draeger Arabia Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/	
TruSignal SpO2 Sensors	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

In vitro diagnostic devices

Accu-Chek Solo diabetes manager	Roche Diabetes Care GmbH	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/	
Alinity ci-series System Control Module (SCM)	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/	
CALiaGold® Calibrator, CALiaGold® Control Set, CALiaGold® Sample Diluent	Sentinel.CH.SpA	Medical Regulations Gate	https://ncmdr.sfda.gov.sa/Secure/CA/	
DxA 5000 Automation System	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/	