

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

23-May-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 02-May-21 من
To 22-May-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): 20 عدد الإجراءات التصحيحية لإنذارات السلامة

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

Venovo Venous Stent System..	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
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Anaesthetic and respiratory devices

Centricity High Acuity Critical Care (CHA CC) and Centricity High Acuity Anesthesia (CHA A) systems	GE Healthcare	GE Healthcare	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
elisa 300, elisa 500, elisa 600, elisa 800 und elisa 800VIT	Lowenstein Medical GmbH &Co.KG	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO	Acutronic Medical Systems AG..	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
MEDUMAT Transport emergency and transport ventilators	Weinmann.	Al Khateeb United Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	

Diagnostic and therapeutic radiation devices

Continuous CT Fluoroscopy DVI Ceiling Mount —CCT Arm DVI Option- Monitor Bracket Assembly	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
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Electro mechanical medical devices

GS777 Wall Transformer (all models) and ProBP 3400 (handheld, desk mount, wall mount models)	Welch Allyn, Inc	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
PrisMax, V2, ROW	Baxter Healthcare	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	

In vitro diagnostic devices

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Access 25(OH) Vitamin D Total for use in Access 2 and Dxl Immunoassay systems	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/	
Access Sensitive Estradiol	Beckman Coulter...	man Coulter Saudi Arabia Co	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
ARCHITECT 2nd Generation Testosterone Reagent Kit	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
AU Creatine Kinase-MB (CK-MB) Reagent	Beckman Coulter...	Beckman Coulter Saudi Arabia Co Ltd	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Immucor GTI Diagnostics LIFECODES MATCH IT!	Immucor GmbH.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Iron Gen.2	Roche Diagnostics GmbH.	e Diagnostics Saudi Arabia Li	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
RX Imola.	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

Reusable devices

ETHICON Linear Cutter	Ethicon Inc.	Johnson Medical Saudi Arab	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Sterile Optical fibers	Quanta System SpA	First Gulf Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	

Single-use devices

BD Venflon Pro Safety (VPS) Needle Protected I.V. Cannula	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
RUSCHELIT Super Safety Clear Tracheal Tube	Teleflex Medical..	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
VHK and VKMO Neonatal	MAQUET Cardiovascular LLC.	Medical Elements	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	