

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

16-Aug-20

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 09-Aug-20 من
To 15-Aug-20 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 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 أو 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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Active Implantable Devices

OMNI II Programmer with OMNI Smart Application Sof	Impulse Dynamics USA Inc.	Medical Technology Trading Company	https://ncmdr.sfda	
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Anaesthetic and respiratory devices

All disposable patient hose systems without a BiCheck flow sensor for the MEDUMAT Transport emergency and transport ventilator	Weinmann.	Al Khateeb United Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15308	
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Dental devices

HYGENIC® Dental Dam Forceps p/n H01262	Coltene Whaledent Inc.	Asnan Medical Services	https://ncmdr.sfda	
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Diagnostic and therapeutic radiation devices

eSie Flow quantification package used with ACUSON SC2000 ultrasound systems and syngo SC2000 Workplace	SIEMENS	Siemens Medical Solutions	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=152	
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Electro mechanical medical devices

Alaris™ Syringe Module Model 8110, Alaris™ PCA Module Model 8120 and Syringe/PCA Sizer Sensor Replacement Kit (P/N 12278652)	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15296	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
BD Alaris™ PC Unit Model 8015 and PC Unit Front Case with Keypad Replacement Kits: (P/N TC10008389, TC10010217, TC10012515, TC10013702, TC10013664)	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15297	
BD Alaris™ Pump Module Model 8100 and Pump Module Door Assembly Replacement Kits	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx	
Intra-Aortic Balloon Catheters, ,	Datascope Corp	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda	
LIFEPAK 15 Monitor/Defibrillato	Stryker	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda	
WASSENBURG DRY210 Drying Cabinets	WASSENBURG Medical B.V.	ARAB DOCTORS EST	https://ncmdr.sfda	

Healthcare facility products and adaptations

Holder for Neonatal and Pediatric Oxygenators	MAQUET Cardiopulmonary GmbH	Medical Elements	https://ncmdr.sfda	
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In vitro diagnostic devices

ALB2 (Albumin Gen.2) & BI LT3 (Bilirubin Total Gen.3)	Roche Diagnostics GmbH.	Roche Diagnostics Saudi Arabia Limited	https://ncmdr.sfda	
Bordetella pertussis Agglutinating Serum, ,	Remel Inc.	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda	
Dimension Vista® System	ens Healthcare Diagnostics G	DULREHMAN AL GOSAIBI G	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
Lactate Dehydrogenase L-P (LDH) (NAD) and Lactate Dehydrognease P-L (UV)	Randox Laboratories Ltd.	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA	
LIAISON® Measles-IgM (318820)	DiaSorin Inc	ABDULLA FOUAD HOLDING COMPANY	https://ncmdr.sfda	

Non-active implantable devices

ALTERA spacer	Globus Medical, Inc	ProMedEx	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe	
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Reusable devices

Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Philips 3.7V Rechargeable Li-Polymer Battery for Expression MR400 MRI Patient Monitoring System Modules	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=15	

Single-use devices

Collection and transport kit	LABWARE MANUFACTURING	BOOL MEDICAL TRADING COM	cure/CA/CaViewRe	
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