

# 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

22-Dec-19

Attached below is the weekly report of Field Safety Corrective Actions (FSCAs) for the period:

مرفق فيما يلي التقرير الأسبوعي للإجراءات التصحيحية للسلامة الميدانية للفترة:

From 14-Dec-19 من  
To 21-Dec-19 إلى

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

و المتأثرة 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 للسلامة الميدانية

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): 17 عدد الإجراءات التصحيحية للسلامة الميدانية:

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

Stellar 100 and 150 Portable Ventilators	ResMed Limited.	Bio Standards	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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### Diagnostic and therapeutic radiation devices

Centricity Universal Viewer	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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FDR Go Mobile X-Ray Systems	Shimadzu Medical Systems.	Al Afandi Establishment	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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Philips VesselNavigator application when used with the Philips Azurion System	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.asp</a>	
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Revolution EVO, Optima CT660 and Optima CT680 CT SmartPrep	GE Healthcare	GE Healthcare	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	
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### Electro mechanical medical devices

Efficia DFM100 Defibrillator/Monitor	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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SLE6000 Infant Ventilator	SLE	him M. Al-Mana & Bros. Co.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
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### Hospital hardware

Eleganza 5 Beds	Linnet spol. s r.o.	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec</a>	
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### In vitro diagnostic devices

BS-800 Chemistry Analyzer	ndray Bio-Medical Electronic	LLA FOUAD HOLDING COM	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
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GSP Neonatal IRT Kit	Wallac Oy	DULREHMAN AL GOSAIBI G	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
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GSP Neonatal IRT Kit	Wallac Oy	DULREHMAN AL GOSAIBI G	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRe</a>	
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Medical Device	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
NycoCard™ D-Dimer ,	Abbott	supplies & Services Co.Ltd M	<a href="#">cure/CA/CaViewRe</a>	
Radiometer ABL90 FLEX and ABL90 FLEX Plus blood gas analysers	Radiometer Medical	Salehiya Trading Est.	<a href="https://ncmdr.sfda.gov.sa/Secure/CA">https://ncmdr.sfda.gov.sa/Secure/CA</a>	
RX Daytona + with ISE & RX Daytona + ,	Randox Laboratories Ltd.	Bio Standards	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	

### Reusable devices

LEGION AP Femoral Cutting Block ,	Smith & Nephew inc	Smith & Nephew inc	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	
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### Single-use devices

EZ-IO Needle + Stabilizer KIT	Teleflex Medical...	irst United Medical Compan	<a href="#">cure/CA/CaViewRe</a>	
ORIGINAL PERFUSOR-TUBING PCA	B. BRAUN MEDICAL INC...	Medical supplies & Services Co.Ltd Mediserv	<a href="https://ncmdr.sfda">https://ncmdr.sfda</a>	