



**To:**

**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
**Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)**  
**Director General of Engineering Affairs, MOH**  
**Director General of Royal Hospital**  
**Director General of Khoula Hospital**  
**Director General of Medical Supplies (MOH)**  
**Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)**  
**Hospital Director (Al Nahda Hospital)**  
**Hospital Director (Al Massara Hospital)**  
**The Head of Medical Services in SQU Hospital**  
**The Head of Medical Services in Royal Oman Police**  
**The Head of Medical Services in Ministry of Defence**  
**The Head of Medical Services in The Diwan**  
**The Head of Medical Services in The Sultan's Special Force**  
**The Head of Medical Services in Internal Security Services**  
**The Head of Medical Services in Petroleum Development of Oman**  
**The Head of Medical Services in LNG Oman**  
**ALL PRIVATE PHARMACIES & DRUG STORES**

**After Compliments,**

**Please find attached our Circular No 190 dated 21/08/2025.**

**Copy to:**

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**



Circular No. **190** / 2025

27-02-1447 H

21-08-2025

Attached below is the weekly report of Safety Alerts for Medical Devices. To identify the affected products and required action, please open the link.

**No. of Safety Alerts 27**

Medical Device	Manufacturer	Link
<b>Active Implantable Devices</b>		
Canturio Smart Extension	Canary Medical, Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Anaesthetic and respiratory devices</b>		
Ambu® SPUR® II	Ambu Inc	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
<b>Assistive products for persons with disability</b>		
Various Joystick	Mo-Vis BVBA	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
<b>Diagnostic and therapeutic radiation devices</b>		
Automated Impella Controller (AIC)	ABIOMED Inc	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
Infinia Series and VG Series Nuclear Medicine systems	GE Healthcare	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Multiva 1.5T MR Systems	Philips Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
Nellcor™ Bedside SpO2 Patient Monitoring System	Covidien LLC....	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
O-arm O2 Imaging System.	Medtronic Navigation, Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>



Medical Device	Manufacturer	Link
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Philips Allura R8.2.x System	Philips Medical Systems Nederland B.V.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
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X-ray High-Voltage Generator	Shimadzu Medical Systems....	<a href="https://apps.tga.gov.au/Prod/DRAC/">https://apps.tga.gov.au/Prod/DRAC/</a>
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#### Electro mechanical medical devices

da Vinci X and Xi Systems	Intuitive Surgical Inc	<a href="https://apps.tga.gov.au/Prod/DRAC/">https://apps.tga.gov.au/Prod/DRAC/</a>
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Heater Unit HU 35	MAQUET Cardiopulmonary GmbH	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
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Hugo™ Robotic-Assisted Surgery (RAS)	Medtronic Inc.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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#### In vitro diagnostic devices

Dexcom G6 OUS	DexCom Inc	<a href="https://apps.tga.gov.au/Prod/DRAC/">https://apps.tga.gov.au/Prod/DRAC/</a>
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GETINGE CM320	Geringe Disinfection AB	<a href="https://apps.tga.gov.au/Prod/DRAC/">https://apps.tga.gov.au/Prod/DRAC/</a>
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Liquid Urine Control Level 3	Randox Laboratories Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
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QUANTA Flash® Centromere Controls	Werfen..	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
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Urinalysis Control Level 2	Randox Laboratories Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
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VITEK 2 AST GN cards	bioMerieux Inc	<a href="https://apps.tga.gov.au/Prod/DRAC/">https://apps.tga.gov.au/Prod/DRAC/</a>
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#### Non-active implantable devices

(Carotid WALLSTENT)	Boston Scientific Corp..	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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POLYCENTRIC 4 BAR MANUAL LOCKING KNEE	Regal Prosthesis	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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#### Reusable devices

Unity ASC femoral sizer	Corin Limited	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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Medical Device	Manufacturer	Link
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### Single-use devices

BD Heyman Follower Straight Tip	C. R. Bard Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
BD Vacutainer® Pronto™ Quick Release Needle Holder	Becton Dickinson & Co. (BD)	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Blood Transfusion Set	Saudi Mais for Medical Products	<a href="https://ade.sfda.gov.sa/Fsca/Publish">https://ade.sfda.gov.sa/Fsca/Publish</a>
Hummingbird	Neurovision Medical Products, Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
lifecath CT PICC easy	Vygon UK Ltd	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>

The local agent shall coordinate with the Drug Safety Center to ensure that appropriate actions are taken in response to the listed alerts. In the event of a safety notice or a defect related to any medical device, the local agent must implement the necessary corrective measures in accordance with Ministerial Decision No. 113/2020, Articles (88) and (89).

Device users are advised to contact the respective local agent to follow up on the implementation of corrective actions needed.

*Sharifa*  
**Dr. Sharifa Amur Al Jabri**  
Acting Director General

