



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 dated 22/12/2025.

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. **216/ 2025**

02-07-1447 H

22-12-2025

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 36**

Medical Device	Manufacturer	Link
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#### Active Implantable Devices

Vanta™ Implantable Neurostimulator	Medtronic Inc.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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#### Diagnostic and therapeutic radiation devices

"MAMMOMAT Revelation; " "MAMMOMAT Inspiration; " MAMMOMAT Fusion;	SIEMENS	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161</a>
Azurion R3.0	Philips Medical Systems Nederland B.V.	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161</a>
Incisive CT, CT 5300.	Philips Healthcare	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217161</a>
Philips Azurion R3.0 Systems	Philips Medical Systems	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Philips Incisive CT and CT 5300 systems	Philips Medical Systems	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Senographe Pristina, Pristina Serena, and Pristina Serena 3D. for screening and diagnostic mammography	GE Healthcare	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=2175">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=2175</a>



Medical Device	Manufacturer	Link
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### Electro mechanical medical devices

Corpuls3 Touch	S Elektromedizinische Geräte G. Stemple Gmb	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Endoscope Reprocessor OER-Pro Endoscope Reprocessor OER-Elite Endoscope Reprocessor OER-Mini	Aizu Olympus Co., Ltd	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216</a>
Ivenix Infusion System (IIS), Large Volume Pump.	Fresenius Kabi	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217296">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217296</a>
IVENIX INFUSION SYSTEM, LVP Primary Administration Set, Dual-Inlet, Low-Sorbing, Needle-Free Port, Dual Y-Site (Qty 25). Large Volume Infusion Pump Administration Set.	Fresenius Kabi	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217296">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217296</a>
MINOP TROCAR	Aesculap...	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Tego Connector - Haemodialysis tubing valve-connector	ICU Medical, Inc	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
Zimmer Air Dermatome and Zimmer Dermatome AN	Zimmer Biomet	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>

### Hospital hardware

BIOSURE REGENESORB (RG) 5×20 mm interference screw	Smith & Nephew inc	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
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## Medical Device

## Manufacturer

## Link

### In vitro diagnostic devices

cobas c 703 Analytical Unit	Roche Diagnostics GmbH.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Combur10 Test M u 411 Visual 100 Str	Roche Diagnostics GmbH.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Get Tested	GET TESTED INTERNATIONAL AB	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Hemochron Activated Clotting Time Low-Range Test Cuvette	Accriva Diagnostics Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
InSure ONE Fecal Immunochemical Test	Enterix, Inc	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
KWIKSTIK	Microbiologies Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
NextSeq™ 550Dx sequencing reagent kits	Illumina Inc	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Serology ToRCH IgM Positive Control	Randox Laboratories Ltd.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>

### Medical software

Vanta™ Clinician Programmer Application	Medtronic Inc.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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### Non-active implantable devices

Abre Venous Self-Expanding Stent System 12-14mm Stent Lots	Medtronic Inc.	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
BIOSURE REGENESORB (RG) 5×20 mm interference screw	Smith & Nephew inc	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
ESOBLOCK @12mm	TEKNIMED SAS.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>



**Medical Device**

**Manufacturer**

**Link**

Locking Screw

Synthes GmbH.

<https://www.bfarm.de/SharedDocs/K>

PALACOS and COPAL Pro Systems

Heraeus Medical GmbH

<https://apps.tga.gov.au/Prod/DRAC/a>

Phantom Fibula Nail, 2.8mm x 130mm,  
Right, Ti, Fibula Nail.

Paragon 28, Inc..

<https://www.accessdata.fda.gov/scr>

**Reusable devices**

Welch Allyn INF BAG, Thigh 1-Tube,  
Two-Piece Blood Pressure Cuff.

Baxter Healthcare

<https://www.accessdata.fda.gov/scr>

**Single-use devices**

Colour Coded Syringes red and blue

Medline Industries Inc

<https://www.bfarm.de/SharedDocs/K>

EVER Pharma D-mine® Pump Reservoir

EVER Neuro Pharma GmbH

<https://www.bfarm.de/SharedDocs/K>

MEDLINE PERFUSION SYRINGE

Medline Industries Inc

<https://www.accessdata.fda.gov/scr>

Riptide™ Aspiration Tubing

icro Therapeutics Inc (DBA ev3 Neurovascula

<https://ade.sfda.gov.sa/Fsca/PublishD>

Safe-T-Centesis 6 Fr Catheter Drainage  
Tray

Bard Peripheral Vascular Inc.

<https://www.accessdata.fda.gov/scr>



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.

**Ph. Ibrahim Nasser Al Rashdi  
Director General**

