



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 205 dated 17/11/2025.

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. **205** / 2025

26-05-1447 H

17-11-2025

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 **34**

Medical Device	Manufacturer	Link
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Diagnostic and therapeutic radiation devices

Multiple devices	hanghai United Imaging Healthcare Co., Ltd...	https://www.accessdata.fda.gov/scr
Multiva 1.5T MR Systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
Philips CT Systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
Sense XL Torso Coil	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishD
ShockPulse Lithotripsy Transducer	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishD

Electro mechanical medical devices

Cardiac Workstation	Philips Healthcare	https://www.accessdata.fda.gov/scr
DVI display cables	Spacelabs Healthcare Inc	https://ade.sfda.gov.sa/Fsca/PublishD
EASY PULSE	Schiller AG	https://ade.sfda.gov.sa/Fsca/PublishD
Kendall SCD 700 Sequential Compression System	Cardinal Health 200, LLC..	https://apps.tga.gov.au/PROD/DRAC/
REANIBEX 300/ REANIBEX 500	Osatu S.Coop.	https://www.bfarm.de/SharedDocs/K
Tempus Pro Monitor	Remote Diagnostic Technologies Ltd..	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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The LIFEPAK 35 Handles	Physio-Control, Inc.	https://apps.tga.gov.au/PROD/DRAC/
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Hospital hardware

HA FlexTrak Trolley	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishD
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In vitro diagnostic devices

3gAllergy Specific IgE Universal Kit	Siemens Healthcare Diagnostics Inc.	https://apps.tga.gov.au/PROD/DRAC/
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Alinity m HIV-1 AMP Kit	Abbott Molecular Division Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
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CAPI 3 IMMUNOTYPING (Product number 2600)	Sebia.	https://www.bfarm.de/SharedDocs/K
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DxC 500i Clinical Analyzer	Beckman Coulter...	https://www.accessdata.fda.gov/scr
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IMMULITE 2000 / IMMULITE 2000 Xpi	Siemens Healthcare Diagnostics Inc.	https://www.bfarm.de/SharedDocs/K
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MAS Omni CARDIO Liquid Assayed Integrated Cardiac Control	Microgenics Corp.	https://www.bfarm.de/SharedDocs/K
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Non-active implantable devices

Dual Mobility Vivacit-E Vitamin E Bearing	Zimmer Biomet	https://www.bfarm.de/SharedDocs/K
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Fuse ULTRA Foot Plating System Instructions for Use.	CPM Medical Consultants, LLC.	https://www.accessdata.fda.gov/scr
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iNSitu Bipolar Hip System, Bipolar head implant	Theken Companies LLC	https://www.accessdata.fda.gov/scr
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Locking Screw	Synthes GmbH.	https://www.accessdata.fda.gov/scr
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Medical Device	Manufacturer	Link
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SUTURE ANCHOR, BIOCOMPOSITE CORKSCREW	Arthrex, Inc	https://apps.tga.gov.au/PROD/DRAC/
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Zip Tight™, Acute AC Joint Implant, Single Ziploop	Zimmer Biomet	https://www.bfarm.de/SharedDocs/K
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Reusable devices

Evis Exera III Duodenovideoscope. Evis Lucera Elite Duodenovideoscope. Duodenovideoscope.	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishDetails/590
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Single-use devices

AVANOS Introducer Kit for Gastrostomy Feeding Tubes	Avanos Medical, Inc...	https://www.bfarm.de/SharedDocs/K
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Baxter CLEARLINK/CONTINU-FLO	Baxter Healthcare	https://www.accessdata.fda.gov/scr
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CODMAN® Disposable Perforator	Integra LifeSciences Production Corporation	https://apps.tga.gov.au/PROD/DRAC/
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DuoDERM" Extra	ConvaTec	https://www.accessdata.fda.gov/scr
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Hemodialysis Bloodlines	B Braun Medical Inc	https://www.accessdata.fda.gov/scr
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Medical convenience kits	American Contract Systems, Inc.	https://www.accessdata.fda.gov/scr
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Medtronic Signia™ Small Diameter Curved Tip Intelligent Reload	Covidien LLC....	https://ade.sfda.gov.sa/Fsca/PublishD
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Setpack/ Toptex Laparotomy Swabs	mann & Rauscher International GmbH & Co.	https://www.bfarm.de/SharedDocs/K
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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**

