



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 208 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. 208 / 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 18

Medical Device	Manufacturer	Link
Active Implantable Devices		
Abbott Liberta Abbott Eterna	Abbott Medical ..	https://www.accessdata.fda.gov/scr
Anaesthetic and respiratory devices		
Affinity NT Oxygenator	Medtronic SA	https://www.accessdata.fda.gov/scr
SimplyGo Mini Portable Oxygen Concentrator. SimplyGo Mini, Standard Battery Kit.	Philips Respironics California	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216
Vapor 2000 and Vapor 3000	Draeger Medical Systems Inc	https://ade.sfda.gov.sa/Fsca/Publish
Diagnostic and therapeutic radiation devices		
Digital Linear Accelerator	Elekta Inc	https://ade.sfda.gov.sa/Fsca/Publish
GM85 Digital Mobile X-ray imaging System	Neurologica Corp.,	https://www.accessdata.fda.gov/scr



Medical Device	Manufacturer	Link
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ProxiDiagnost N90 / Precision CRF (706110, 706400 "DigitalDiagnost C90 " "Radiography 7300 C " DigitalDiagnost CombiDiagnost R90	Philips Medical Systems	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216491
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Sonesta	Sonesta Medical AB..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216491
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Electro mechanical medical devices

Giraffe OmniBed and Giraffe OmniBed Carestation devices	Datex - Ohmeda Inc	https://ade.sfda.gov.sa/Fsca/Publish
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In vitro diagnostic devices

ORTHO VISION BioVue Cassettes and Max Analyser for BioVue Cassettes. An in vitro diagnostic medical device (IVD)	Ortho-Clinical Diagnostics	https://apps.tga.gov.au/Prod/DRAC/arn-detail.aspx?k=RC-2025-RN-
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SYNCHRON Systems Direct LDL Cholesterol (LDLD) Reagent	Beckman Coulter...	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216491
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VITROS® Chemistry Products Performance Verifier I (PV I)	Ortho-Clinical Diagnostics	https://ade.sfda.gov.sa/Fsca/Publish
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Laboratory equipment

BD Kiestra" Isolate Suspension Cuvette Array	Becton Dickinson & Co. (BD)	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216491
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Medical Device	Manufacturer	Link
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Non-active implantable devices

BEAR Implant (Bridge-Enhanced ACL Restoration)	Miach Orthopaedics	https://www.accessdata.fda.gov/scrrips/
Virata Preassembled Polyaxial Screw, utilized in the Virata Spinal Fixation System	Orthofix	https://www.accessdata.fda.gov/scrrips/cdrh/cfdocs/cfRES/res.cfm?id=216

Reusable devices

TPSG2 RoboMarker G2 Tip	Surgilum LLC	https://apps.tga.gov.au/Prod/DRAC/
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Single-use devices

HYBRID straight guidewire device	Balt Extrusion	https://www.bfarm.de/SharedDocs/K
Medline Renewal LigaSure Maryland Jaw Sealer/Divider Medline Renewal LigaSure Impact Curved Large Jaw Sealer/Divider Medline Renewal Ligasure Blunt Tip Sealer/Divider Medline Renewal Ligasure Blunt Tip Sealer/Divider Medline Renewal LigaSure Small Ja	Medline Industries Inc	https://www.accessdata.fda.gov/scrrips/cdrh/cfdocs/cfRES/res.cfm?id=216_659



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

