

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 97 dated 08/10/2026.

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Department, DSC**
- **Director of Pharmacovigilance Department, DSC**
- **Director of Medicine Registration Department, DSC**
- **Director of Regulatory Compliance Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

Circular No. 97 / 2026

26 -04-1448 H

08 -10-2026

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
Diagnostic and therapeutic radiation devices		
Philips Azurion and Allura Systems	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Philips CT Rembra systems	Philips Healthcare	https://apps.tga.gov.au/Prod/DRAC/a
Electro mechanical medical devices		
Citrasate, GRANUFLO and Naturalyte	Fresenius Medical Care.	https://www.accessdata.fda.gov/scr
DermaV Laser System	Lutronic Corporation...	https://www.accessdata.fda.gov/scr
HeartHero Elliot Automated External Defibrillator (AED)	HeartHero Inc	https://apps.tga.gov.au/Prod/DRAC/a
TCM Tosca and TCM CombiM	Radiometer Medical ApS	https://apps.tga.gov.au/Prod/DRAC/a
The HeartSine samaritan	HeartSine Technologies Ltd..	https://www.accessdata.fda.gov/scr
Hospital hardware		
Electric Table HE Spectralis BW	CX Engineering sp. z o.o.	https://www.bfarm.de/SharedDocs/K
In vitro diagnostic devices		
Anti-Annexin V IgG	ORGENTEC Diagnostika GmbH...	https://www.bfarm.de/SharedDocs/K
Medical software		
IntelePACS – InteleConnect Portal / Tech Portal Version	Intelerad Medical Systems Inc..	https://apps.tga.gov.au/Prod/DRAC/a

Medical Device	Manufacturer	Link
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Non-active implantable devices

Shockwave REDUCER Kits	Shockwave Medical, Inc..	https://www.bfarm.de/SharedDocs/K
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Not related to a medical device

Aspire Active Air 8 Pressure Care Air Mattress	Aidacare Pty Ltd	https://apps.tga.gov.au/Prod/DRAC/a
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Reusable devices

RAPICIDE PA High-Level Disinfectant	STERIS Corporation....	https://www.bfarm.de/SharedDocs/K
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Single-use devices

CliniClean Pericare Wipes within SureStep™ Foley Tray System Bard™ Lubri-Sil™ Foley Catheter Tray	C.R. BARD...	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2199
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Convenience kits	Medical Action Industries Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2199
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Geringe PVC Thoracic Catheter	Atrium Medical Corporation..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2199
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Halyard IV Start Kit Non-Sterile	Avid Medical, Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2199
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Trays and Packs Containing CliniClean Pericare Wipes	Cardinal Health 200, LLC..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2199
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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

