



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 04 dated 13/01/2026.

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. 04 / 2026

24 -07-1447 H

13 -01-2026

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 15

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
Drive Devilbiss Home CPAP Unit	Drive DeVilbiss	https://apps.tga.gov.au/PROD/DRAC/
High-Frequency Jet Ventilator	Thora Tech GmbH	https://www.bfarm.de/SharedDocs/K
Assistive products for persons with disability		
Swivel standing aid	Burmeier GmbH & Co. KG	https://www.bfarm.de/SharedDocs/K
Dental devices		
AQUASIL PUTTY - SOFT and HARD	DENTSPLY International	https://apps.tga.gov.au/PROD/DRAC/
Diagnostic and therapeutic radiation devices		
MR systems with SW version R11.1 and R12.1	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Vortex Surgical 25ga Illuminated Flex-Tip Laser Probe	Vortex Surgical Inc	https://www.accessdata.fda.gov/scr
Electro mechanical medical devices		
- neXus V700 Infusion Pump - neXus S700 Syringe Pump	BD Switzerland Sarl	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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Bubble Sensor	MAQUET Cardiopulmonary GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/684
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In vitro diagnostic devices

EliA™ ANA Positive Control 250, EliA™ ANA Positive Control 2500/5000 and EliA™ ANA Positive Control 200	ThermoFisher.	https://ade.sfda.gov.sa/Fsca/PublishDetails/684
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IDS iSYS Trigger Set	Immunodiagnostic Systems SA	https://apps.tga.gov.au/PROD/DRAC/
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Medical software

RayStation/RayPlan 10B, 11A, 11B, 12A, 2023B, 2024A, 2024B and v2025 including some service packs.	RaySearch Laboratories AB (publ)	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/18/2025/57335-
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Single-use devices

da Vinci Single Port System Access Port Kits	Intuitive Surgical Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/18/2025/57335-
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Osteobell T OB1110T Biopsy needles	Biopsybell SRL	https://apps.tga.gov.au/PROD/DRAC/
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Sentinel Seal™, Altitude™, Aqua-Seal™, ThoraSeal™ Chest Drainage Units & accessories	Cardinal Health 200, LLC..	https://ade.sfda.gov.sa/Fsca/PublishDetails/680
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SMSCOZYM SPONGES	Saudi Medical Solution Company	https://ade.sfda.gov.sa/Fsca/PublishDetails/680
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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.

Shanifa

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

