



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 67 dated 29/06/2026.

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. 67 / 2026

14-01-1448 H

29-06-2026



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 48

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Assistive products for persons with disability		
Lotus stand-up aid	LOPITAL NEDERLAND B.V.	https://www.bfarm.de/SharedDocs/K
Molift Mover 205 Floor Lifter	Novis Healthcare Pty Ltd	https://apps.tga.gov.au/PROD/DRAC/
Biologically-derived devices		
Avitene Ultrafoam Microfibrillar Collagen Hemostat	Davol, Inc	https://www.accessdata.fda.gov/scrrip
nanOss 3D	XTANT MEDICAL INC	https://www.accessdata.fda.gov/scrrip
Dental devices		
Adhese 2 DC VivaPen Kits and DC Cannulas for VivaPen	Ivoclar Vivadent AG..	https://www.bfarm.de/SharedDocs/K
Diagnostic and therapeutic radiation devices		
3Dimensions Mammography System, Selenia Dimensions Mammography System	Hologic Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/794



Medical Device	Manufacturer	Link
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Allia IGS systems	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
AW Server deployed via Edison Health Link (EHL)	GE Healthcare	https://www.bfarm.de/SharedDocs/K
Gentuity HF-OCT Imaging System	Gentuity, LLC	https://www.accessdata.fda.gov/scrip
MiniUV, UVO , Uvlizer, Uvlizer Tower, Uvlizer Home Disinfecting Device	Uvlizer c/o RAIS INTERNATIONAL LLC	https://www.accessdata.fda.gov/scrip
Philips Spectral CT on Rails	Philips Medical Systems	https://www.accessdata.fda.gov/scrip
Rover Mobile XRay System	Micro-X Ltd	https://www.accessdata.fda.gov/scrip

Electro mechanical medical devices

da Vinci X, Xi systems Universal Surgical Manipulator (USM)	Intuitive Surgical Inc	https://www.bfarm.de/SharedDocs/K
Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	https://ade.sfda.gov.sa/Fsca/PublishDetails/796

Hospital hardware

HILL-DT Decompression Table	HILL Laboratories Ltd	https://www.bfarm.de/SharedDocs/K
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In vitro diagnostic devices

Access Total T4 Calibrator	Beckman Coulter...	https://www.accessdata.fda.gov/scrip
Artisan Periodic Acid-Schiff Stain Kit, Artisan Alcian Blue/PAS Stain Kit, Artisan PAS-Green Stain Kit, and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit	Dako North America Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/797
BRAHMS PIGF Plus KRYPTOR	BRAHMS GmbH	https://apps.tga.gov.au/PROD/DRAC/



Medical Device	Manufacturer	Link
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Exposure Test Carrier (ETC)	Werfen..	https://www.bfarm.de/SharedDocs/K
Rx Modena	Radox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD
Sequencing Agent SEQ0067, component of FoundationOne CDx (F1CDx)	Foundation Medicine, Inc..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2192
URINALYSIS CONTROL - LEVEL 2.	Radox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD

Laboratory equipment

EXENT Analyser IQ Software	The Binding Site	https://apps.tga.gov.au/PROD/DRAC/
Magellan Diagnostics LeadCare Plus Blood Lead Test Kit, Magellan Diagnostics LeadCare Ultra Blood Lead Test Kit	Magellan Diagnostics Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218942

Medical software

CGM CLINICAL Medication, CGM CLINICAL Assessments and CGM CLINICAL Liquid Balance	CompuGroup Medical Deutschland AG	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/09/2026/16949-
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Non-active implantable devices

Everest MI 1 Level Kit	Stryker Orthopaedics	https://www.bfarm.de/SharedDocs/K
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Ophthalmic and optical devices

Eyevisc 2% 2mL PFS	BIOTECH VISION CARE PVT. LTD	https://www.bfarm.de/SharedDocs/K
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Medical Device	Manufacturer	Link
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Reusable devices

OER-ELITE Endoscope Reprocessor Connecting Tubes	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scrrip
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Single-use devices

Angiodyn Angiographic Catheter 5F IM	PendraCare International B.V...	https://www.bfarm.de/SharedDocs/K
Captura Pro Biopsy Forceps	Wilson-Cook Medical Inc.	https://apps.tga.gov.au/PROD/DRAC/
CENTURION Circumcision Kit	Medline Industries Inc	https://www.accessdata.fda.gov/scrrip
CUSA Clarity Console	Integra LifeSciences	https://www.accessdata.fda.gov/scrrip
Custom Convenience Kits Pre Op Kit - NS	Windstone Medical Packaging, Inc..	https://www.accessdata.fda.gov/scrrip
Flamingo Funnel Medium (also referred to as microSQUAIR)	SurgiSmoke Solutions	https://www.accessdata.fda.gov/scrrip
HALYARD* PUREZERO* Ultraviolet* Nitrile Exam Gloves	Owens & Minor	https://www.bfarm.de/SharedDocs/K
Injector Syringe Dual	Saudi Mais for Medical Products	https://ade.sfda.gov.sa/Fsca/PublishD
Kaleido Insulin Infusion System	ViCentra B.V.	https://www.bfarm.de/SharedDocs/K
Kiwi Complete Vacuum Delivery System	Laborie Medical Technologies, Corp.	https://www.bfarm.de/SharedDocs/K
MANUSHIELD CLEANER	Dr. Schumacher GmbH.	https://www.bfarm.de/SharedDocs/K
Multiple devices	Medline Industries Inc	https://www.accessdata.fda.gov/scrrip
Multiple devices	Medline Industries Inc	https://www.accessdata.fda.gov/scrrip
Multiple devices	Arrow International Inc	https://www.accessdata.fda.gov/scrrip
Multiple devices	LSL Healthcre Inc.	https://www.accessdata.fda.gov/scrrip



Medical Device	Manufacturer	Link
Namic Angiographic Control Syringe with Rotating Adaptor (RA) fitting (Namic RA syringes)	Medline International France SAS.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2026/16457-26_kundeninfo_en.pdf?__blob=public
Soft-Vu, Angiographic Catheter	AngioDynamics, Inc .	https://www.accessdata.fda.gov/scr
The Multi-Snare	pfm medical ag, pfm medical mepro	https://www.bfarm.de/SharedDocs/K
THERAKOS® CELLEX® Photopheresis Procedural Kit	Mallinckrodt Pharmaceuticals Ireland Limited	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**

