



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 44 dated 21/04/2026.

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. 44 / 2026

03-11-1447 H

21-04-2026



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 64

Medical Device	Manufacturer	Link
Active Implantable Devices		
Impella RP	ABIOMED Inc	https://www.bfarm.de/SharedDocs/K
Anaesthetic and respiratory devices		
BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2024/20133-
Sentinel Cardiology Information Management System	Spacelabs Healthcare Inc	https://www.bfarm.de/SharedDocs/K
Trilogy Evo, Trilogy Evo O2, Trilogy EV300	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Assistive products for persons with disability		
Quha Zono X gyroscopic mouse	Quha	https://www.bfarm.de/SharedDocs/K
Diagnostic and therapeutic radiation devices		
Hitachi Proton Beam Therapy System	Hitachi, Ltd.	https://www.accessdata.fda.gov/scr
Imactis CT-Navigation system	GE Healthcare	https://apps.tga.gov.au/PROD/DRAC/



Medical Device	Manufacturer	Link
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Philips Interventional Hemodynamic System	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
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THUNDERBEATTM Hand Instrument	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scrrip
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Electro mechanical medical devices

Barco MNA with the HexaVue IP Integration System	STERIS Corporation.	https://www.accessdata.fda.gov/scrrip
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BD Alaris neXus and Alaris Plus syringe pumps	Becton Dickinson & Co. (BD)	https://ade.sfda.gov.sa/Fsca/PublishD
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da Vinci 5 Surgeon Console Viewer Display, ASSY, DV5 CONSOLE.	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scrrip
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Da Vinci 5 ASSY, DV5 CONSOLE	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scrrip
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Datascope Cardiosave Hybrid and Rescue Intra-Aortic Balloon Pumps (IABP)	Getinge	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/23220-
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Erbe Cryoprobe	ERBE Elektromedizin GmbH	https://www.bfarm.de/SharedDocs/K
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Erbe Cryoprobe	ERBE Elektromedizin GmbH	https://apps.tga.gov.au/PROD/DRAC/
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Essenza 300	Linet spol. s r.o..	https://ade.sfda.gov.sa/Fsca/PublishD
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Hugo™ RAS System	Medtronic SA	https://ade.sfda.gov.sa/Fsca/PublishD
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InterPulse® Irrigation System	Stryker Instruments.	https://www.bfarm.de/SharedDocs/K
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MONARCH Platform, Bronchoscopy.	Auris Health, Inc.	https://www.accessdata.fda.gov/scrrip
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MRI LED Mobile Exam Light Battery	MRIMed Inc.	https://www.accessdata.fda.gov/scrrip
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Olympus Cystoscope Outer Sheath	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scrrip
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Medical Device	Manufacturer	Link
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PIE PAK, PIE Trolley System	Edermy LLC	https://www.accessdata.fda.gov/scrrip
Spectrum IQ	Baxter Healthcare	https://www.accessdata.fda.gov/scrrip
Teslatome Bipolar Sphincterotomes	Wilson-Cook Medical Inc.	https://www.accessdata.fda.gov/scrrip

Hospital hardware

CLARITY II	Lutronic Corporation...	https://www.bfarm.de/SharedDocs/K
corpuls1	S Elektromedizinische Geräte G. Stemple Gmb	https://www.bfarm.de/SharedDocs/K
XTAR USB LCD Li-ion Battery Charger	Shenzhen XTAR Electronics Co., Ltd	https://www.bfarm.de/SharedDocs/K

In vitro diagnostic devices

Estrone RIA	IMMUNOTECH s.r.o.	https://www.accessdata.fda.gov/scrrip
Medica Capillary Tubes	Medica Corporation,,	https://www.accessdata.fda.gov/scrrip

Laboratory equipment

VITROS XT 3400 and 4600 Chemistry Systems, and VITROS 5600 and XT 7600 Integrated Systems.	Ortho-Clinical Diagnostics	https://ade.sfda.gov.sa/Fsca/PublishDetails/735
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Medical software

Automated Impella Controllers (AICs) with Software Version 8.5, used in conjunction with an Impella 5.5 S1	ABIOMED Inc	https://apps.tga.gov.au/PROD/DRAC/arm-detail.aspx?k=RC-2026-RN-
CGM CLINICAL Assessments	CompuGroup Medical Deutschland AG	https://www.bfarm.de/SharedDocs/K
DeepUnity PACSonWEB	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Anesthesia	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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Non-active implantable devices

Endo-Model M - Instrument	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/K
Gelsoft Plus	Terumo Cardiovascular Systems Corp	https://www.bfarm.de/SharedDocs/K
HAPTic® rasp proximal sz. 1-5	Implantcast	https://www.bfarm.de/SharedDocs/K
Hip Prosthesis Stem XL Neck, cemented, L= 150 mm, left L3, large, CCD 126°, CoCrMo, anatomical, Taper 12/14	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2026/05978-26_kundeninfo_en.pdf?blob=public
LINK Prosthesis Head B	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/K
LINK Prosthesis Heads B	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/K
MOLLI 2 System	Stryker Communications.....	https://www.accessdata.fda.gov/scrip
Prodisc C SK	Centinel Spine, Inc	https://www.accessdata.fda.gov/scrip
Reverse Shoulder Prosthesis (RSP), EMPOWR 3D KNEE	Encore Medical, L.P..	https://www.accessdata.fda.gov/scrip

Ophthalmic and optical devices

- marFocus grey optics - marFocus blue optics - marScan grey optics	KLS Martin GmbH + Co. KG	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/14/2026/08858-
EVO+ Visian Toric Implantable Collamer® Lens (TICL)	STAAR Surgical AG.	https://ade.sfda.gov.sa/Fsca/PublishD

Reusable devices

Broselow Rainbow Tape (2025 Edition, 36-23446 Rev 3)	AirLife	https://apps.tga.gov.au/PROD/DRAC/
Single use Biopsy Valves	Olympus Corporation of the Americas .	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
Single-use devices		
16F Dual-Valved Splittable Sheath Introducer	Merit Medical Systems Inc....	https://www.bfarm.de/SharedDocs/K
Broviac and Hickman catheter, different sizes.	Bard Peripheral Vascular Inc.	https://www.accessdata.fda.gov/scrip
Comvita Medihoney Antibacterial Wound Gel 25 gram & 50 gram	Derma Sciences, Inc	https://apps.tga.gov.au/PROD/DRAC/
Esteem Body	ConvaTec	https://www.bfarm.de/SharedDocs/K
HistoPot 180ml	Serosep Limited	https://ade.sfda.gov.sa/Fsca/PublishD
IV Line Volved Set, Polypropylene, 330cm, 2x Needle Free Connectors	PHOENIX SRL.	https://apps.tga.gov.au/PROD/DRAC/
MediHoney and Private Label CVS.	Derma Sciences, Inc	https://www.accessdata.fda.gov/scrip
Medline Convenience Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
Medline Industries IV Administration and Extension Sets.	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
MiniMed™ Paradigm™, MiniMed™ 600 series, and MiniMed™ 700	Medtronic SA	https://www.bfarm.de/SharedDocs/K
Multiple products	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
Sagittal Blade	Stryker Instruments.	https://www.bfarm.de/SharedDocs/K
Saline Wound Wash, Medline Convenience Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
Surgilube Sterile Lubricating Gel 2.7g sachets x 144 pack	Sion Biotext Medical Ltd	https://apps.tga.gov.au/PROD/DRAC/
Ventilator Breathing Circuit for Non-invasive Ventilation Devices	Armstrong Medical Ltd..	https://apps.tga.gov.au/PROD/DRAC/



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

