



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 49 dated 11/05/2026.

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. 49 / 2026

23-11-1447 H

11-05-2026



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 40

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
BiPAP A40 Pro Ventilator, BiPAP A40 EFL Ventilator, and BiPAP A30 EFL Ventilator	Respironics Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/138
PALAMIX® uno and PALAMIX® duo	Heraeus Medical GmbH	https://ade.sfda.gov.sa/Fsca/PublishD
Biologically-derived devices		
Artegraft Vascular Graft;	LeMaitre Vascular, Inc.	https://www.accessdata.fda.gov/scr
Diagnostic and therapeutic radiation devices		
AneurysmFlow	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Leksell® Vantage Arc System	Elekta Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Spectral CT 7500 systems.	Philips Healthcare	https://apps.tga.gov.au/PROD/DRAC/
Electro mechanical medical devices		
EVO IQ Large Volumetric Pumps (LVP).	Baxter Healthcare	https://apps.tga.gov.au/PROD/DRAC/
HF (high-frequency) bipolar cable	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device	Manufacturer	Link
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marClamp Cut IQ mit Instrumentenkod.23cm	KLS Martin GmbH + Co. KG	https://www.bfarm.de/SharedDocs/K
Radius VSM ECG Electrodes and Pressure Cuffs	Masimo Corporation	https://www.bfarm.de/SharedDocs/K
THUNDERBEAT™ II Shears with Ultrasonic Mode	Gyrus ACMI, Inc.	https://www.bfarm.de/SharedDocs/K
TRUE METRIX Blood Glucose Monitoring Systems	Trividia Health	https://www.accessdata.fda.gov/scrip

Hospital hardware

Cub Pediatric Crib	Stryker Instruments.	https://www.accessdata.fda.gov/scrip
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In vitro diagnostic devices

Access Total T4 Calibrators	Beckman Coulter...	https://ade.sfda.gov.sa/Fsca/PublishD
Aptima HPV Assay	Hologic Inc.	https://www.accessdata.fda.gov/scrip
Bisaf Strep A Self-Test, Clearest Strep-A Cassette Test, Wondfo Streptococcal A At-Home Self-Test	Altruan GmbH	https://www.accessdata.fda.gov/scrips/cdrh/cfdocs/cfres/res.cfm?id=2188
EdgeSuite	In Log S.A.S	https://www.bfarm.de/SharedDocs/K
HemosIL Heparin Calibrators	Werfen..	https://apps.tga.gov.au/PROD/DRAC/
ipsogen BCR-ABL1 mbcr Kit. An in vitro diagnostic medical device (IVD).	QIAGEN Ltd	https://www.bfarm.de/SharedDocs/K
STA Liatest D-Di Plus	Diagnostica Stago S.A.S.	https://www.accessdata.fda.gov/scrip
The DermaGenius® 3.0 Complete Multiplex real-time PCR kit	PathoNostics B.V.	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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Medical software

ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K

Non-active implantable devices

ARTIS PL E and ARTIS SYMBIOSE ranges	Cristalens Industrie	https://www.bfarm.de/SharedDocs/K
E-tegra Stent Graft System E-nside TAAA Multibranch Stent Graft System E-vita OPEN NEO	Artivion, Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2026/05107-26_kundeninfo_en.pdf? blob=public
Multiple devices	I.T.S. GmbH..	https://www.accessdata.fda.gov/scrip
Novuma Collagen Stimulating Dermal Filler	BURGEON BIOTEKNOLOJI VE SAN.TIC.A.S	https://www.bfarm.de/SharedDocs/K
Thoraflex Hybrid	Terumo Cardiovascular Systems Corporation.	https://www.bfarm.de/SharedDocs/K

Ophthalmic and optical devices

Eyevisc	BIOTECH VISION CARE PVT. LTD	https://www.bfarm.de/SharedDocs/K
Welch Allyn Spot Vision Screener VS100	Baxter Healthcare	https://www.accessdata.fda.gov/scrip

Reusable devices

MICS3 Angled Sagittal Saw Attachment	Howmedica Osteonics Corp.	https://www.accessdata.fda.gov/scrip
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Medical Device	Manufacturer	Link
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Single-use devices

EsteemBody Drainable Pouch	ConvaTec	https://www.accessdata.fda.gov/scríp
Instinct Plus Endoscopic Clipping Device	Wilson-Cook Medical Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
IVascular navitian	Life Vascular Devices Biotech S.L	https://ade.sfda.gov.sa/Fsca/PublishD
Medline Kits containing Cardinal Health s Aqua-Seal Chest Drainage Unit	Medline Industries Inc	https://www.accessdata.fda.gov/scríp
Medline Medcrest Surgical Gowns, Medline Surgical Drapes	Medline Industries Inc	https://www.accessdata.fda.gov/scríp
Medtronic Sphere-9 Catheter	Medtronic SA	https://apps.tga.gov.au/PROD/DRAC/
Soft-Vu, Angiographic Catheter	AngioDynamics, Inc .	https://apps.tga.gov.au/PROD/DRAC/
ULTRAVIT and HYPERVIT probes	Alcon Laboratories Inc....	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

