



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 43 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. 43 / 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 28

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
FlurAbsorb Pro-S and FlurAbsorb Pro- L	Sedana Medical AB	https://www.bfarm.de/SharedDocs/K
Assistive products for persons with disability		
<ul style="list-style-type: none">- High-low:xo (all configurations and all sizes)- Wombat Living (all configurations and all sizes) with production date newer than 2023-02-08- x:panda shape TS (all configurations and all sizes)	Etac Supply Center AB.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/15/2026/04423-26_kundeninfo_en.pdf? blob=publicationFile
MRDSET-NSW (Mechanical Restraint Device Set)	Hemco Industries Pty Ltd	https://apps.tga.gov.au/PROD/DRAC
Diagnostic and therapeutic radiation devices		
FDR Visionary Suite	FUJIFILM Medical Systems	https://www.accessdata.fda.gov/scr
Leksell Gamma Knife	Elekta Inc	https://apps.tga.gov.au/PROD/DRAC



Medical Device	Manufacturer	Link
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Electro mechanical medical devices

Nutricia Flocare Infinity III Enteral Feeding Pump	Nutricia Medical Devices	https://apps.tga.gov.au/PROD/DRAC
CADD High Volume Administration Sets	ICU Medical, Inc	https://www.bfarm.de/SharedDocs/K
IMMULITE 2000 EPO & IMMULITE EPO Control Module	Siemens Healthcare Diagnostics Inc.	https://apps.tga.gov.au/PROD/DRAC
Kangaroo Power Cord and Enteral Feeding Pumps	Cardinal Health 200, LLC..	https://apps.tga.gov.au/PROD/DRAC

Hospital hardware

Laerdal Compact Suction Unit 4	Laerdal Medical AS.	https://www.accessdata.fda.gov/scrrip
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In vitro diagnostic devices

Actim® PROM Ingeni Test (30832RETAL)	Actim Oy.	https://www.bfarm.de/SharedDocs/K
Lumipulse G pTau217/B-Amyloid 1-42 Plasma Ratio	Fujirebio Diagnostics, Inc.	https://www.accessdata.fda.gov/scrrip
STA Liatest D-Di Plus	Diagnostica Stago S.A.S.	https://ade.sfda.gov.sa/Fsca/Publish
VITROS Immunodiagnostic Products Progesterone 2 Calibrators and Reagent Pack	Ortho-Clinical Diagnostics	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2026-RN-
VITROS XT 3400/3600/4600/5600/XT 7600 Systems.	Ortho-Clinical Diagnostics	https://ade.sfda.gov.sa/Fsca/Publish

Non-active implantable devices

ATEC Lateral Navigation Disc Prep Instruments	Alphatec Spine Inc	https://www.accessdata.fda.gov/scrrip
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Medical Device	Manufacturer	Link
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Ergo Impactor Handle	Exactech	https://www.bfarm.de/SharedDocs/K
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H3 Hintermann Ankle Replacement System	DT MedTech	https://apps.tga.gov.au/PROD/DRAC
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Single-use devices

AquaUltra Clear	Ultragel 2000 Hungary Kft	https://www.bfarm.de/SharedDocs/K
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AXIOS™ Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific Corp..	https://www.accessdata.fda.gov/scrrip
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Clinell Universal Wipes	GAMA Healthcare Ltd.	https://apps.tga.gov.au/PROD/DRAC
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Extra-Corporeal Circuit Tube	Tianjin Plastics Research Institute Co., Ltd.	https://www.bfarm.de/SharedDocs/K
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Halyard TRANSPORT BAG KIT. Kit Code: LIFE0080-01.	Avid Medical, Inc.	https://www.accessdata.fda.gov/scrrip
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Intubation Tray and Suction Catheter.	Medline Industries Inc	https://www.accessdata.fda.gov/scrrip
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Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter, Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter, Medline ReNewal Reprocessed BW Webster CS Catheter with EZ Steer Technology; and Auto ID Technology, Medline ReNewal Reproces	Medline Industries Inc	https://www.accessdata.fda.gov/scrrips/cdrh/cfdocs/cfRES/res.cfm?id=218_102
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Multiple devices	Medline Industries Inc	https://www.accessdata.fda.gov/scrrip
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OLYMPUS CleverCut and FlowCut Sphincterotomes	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scrrip
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Vortex Surgical Kit, Volk, Tecfen, Oertli and Rumex.	Vortex Surgical Inc	https://www.accessdata.fda.gov/scrrip
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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

