



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 75 dated 27/07/2026.

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. 75 / 2026

12-02-1448 H

27-07-2026

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 35

Medical Device	Manufacturer	Link
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Active Implantable Devices

Automated Impella Controller (AIC)	ABIOMED Inc	https://www.accessdata.fda.gov/scr
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Diagnostic and therapeutic radiation devices

ARTIS icono Ceiling System	Siemens Healthcare GmbH	https://apps.tga.gov.au/PROD/DRAC/
CyberKnife® System	Accuray Inc	https://ade.sfda.gov.sa/Fsca/PublishD
MAVIG monitor suspension	GE Healthcare	https://www.bfarm.de/SharedDocs/K
O-arm™ O2 Imaging System	Medtronic Inc.	https://www.accessdata.fda.gov/scr
Radiography 7000 M	Philips Medical Systems	https://apps.tga.gov.au/PROD/DRAC/
SUPER MOBILE	MITO RED LIGHT INC	https://www.accessdata.fda.gov/scr

Electro mechanical medical devices

Bicarby Dialysate	Fresenius Medical Care.	https://www.accessdata.fda.gov/scr
FARASTAR Pulsed Field Ablation Generator - FARAPOINT PFA Catheters	Boston Scientific Neuromodulation Corporation.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/10/2026/26008-
High Flow Insufflation Unit	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishD
LIFEPAK 15 V4 – SpCO/SpMet Sensor	Stryker Communications.....	https://www.bfarm.de/SharedDocs/K



Medical Device

Manufacturer

Link

Healthcare facility products and adaptations

Harmony AIR A-Series & ALYON Surgical Lighting System	STERIS Corporation....	https://www.accessdata.fda.gov/scr
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In vitro diagnostic devices

Atellica CH Enzymatic Haemoglobin A1c (A1c_E) used with Atellica CH and Atellica CI systems.	Siemens Healthcare Diagnostics Inc	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2026-RN-
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directCHECK ACT-LR whole blood quality control	Accriva Diagnostics Inc.	https://www.accessdata.fda.gov/scr
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Idylla™ MSI Test	Biocartis NV.	https://www.bfarm.de/SharedDocs/K
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Medical software

Dexcom G6 Android app	DexCom Inc	https://www.bfarm.de/SharedDocs/K
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N/A

Fresh Roast Systems ColorTrack.	Fresh Roast Systems Inc	https://www.accessdata.fda.gov/scr
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Non-active implantable devices

ACS® Uni IM adapter	Implantcast	https://www.bfarm.de/SharedDocs/K
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Boston Scientific Model SC-4318, Klik X Anchor	Boston Scientific Neuromodulation Corporation.	https://www.accessdata.fda.gov/scr
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TRI TS BASEPLATE SIZE 4 & 3	Howmedica Osteonics Corp.	https://www.accessdata.fda.gov/scr
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Reusable devices

Integra® Omni-Tract® Surgical Retractor System	Integra LifeSciences	https://www.bfarm.de/SharedDocs/K
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Medical Device	Manufacturer	Link
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Single-use devices

Arrow Kits and Sets that contain Lidocaine and Bupivacaine	Arrow International Inc	https://www.accessdata.fda.gov/scr
BD Connecta™ Stopcock in L&R Kitpacks	Lohmann & Rauscher International GmbH & Co. KG	https://www.bfarm.de/SharedDocs/K
Biopsy forceps	Fehling Instruments GmbH & Co KG	https://www.bfarm.de/SharedDocs/K
FARADrive Steerable Sheath	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishD
Halyard, Eye Bag Pack. Halyard, Drape Pack. Halyard, Towel Six Pack Halyard, Pain Pack.	Avid Medical, Inc.	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2205 15
MAJ-2315 Single Use Distal Cover	Olympus Europa SE & CO.KG..	https://apps.tga.gov.au/PROD/DRAC/
Medline convenience kits. MINOR CATH LAB PACK. OR VASCULAR ANGIO PACK. PORT-A-CATH. BLOCK TRAY. INDWELLING NERVE BLOCK. Centurion convenience kits. Multiple devices, refer to attached file.	Medline Industries Inc	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2203 75
MEDLINE Medical Procedures Kits. Urethral Catheterization products. Intermittent Latex Catheter Coude	Medline Industries Inc	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2204
Orca Single Use Air/Water and Suction Valves	Boston Scientific Corp..	https://www.accessdata.fda.gov/scr
Penumbra System RED 68 Reperfusion Catheter	Penumbra, Inc...	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device	Manufacturer	Link
ProSet Infusomat Space Line, PVC, DiscofixC, Intrapur Lipid 1,2µm	B Braun Medical Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2026/25216-
Ritmed Neurological Sponges	AMD Medicom Inc.	https://www.accessdata.fda.gov/scr
SECUTRAY procedure packs containing BD Connecta™M Stopcocks	Sengewald Klinikprodukte GmbH	https://www.bfarm.de/SharedDocs/K
TiLOOP Total Catheter	pfm medical ag, pfm medical mepro	https://www.bfarm.de/SharedDocs/K



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**

