

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 98 dated 08/10/2026.

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. 98 / 2026

26 -04-1448 H

08 -10-2026

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 38

Medical Device	Manufacturer	Link
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Active Implantable Devices

Nucleus CI612 cochlear implant	Cochlear AG	https://www.bfarm.de/SharedDocs/K
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Anaesthetic and respiratory devices

IPV Systems (IPV 1; IPV-1C; IPV-2C; Impulsator; Travel Air; IPV-HC)	Percussionaire Corporation.	https://www.accessdata.fda.gov/scr
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NOxBOXi Nitric Oxide Delivery System	NOxBOX Ltd.	https://www.accessdata.fda.gov/scr
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Precision Pointer Electro Magnetic (EM)	Stryker Communications.....	https://www.bfarm.de/SharedDocs/K
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Diagnostic and therapeutic radiation devices

ARTIS icono / pheno system with version VE50B	Siemens Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
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Multiva 1.5T MR Systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
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Positron emission tomography and computed tomography x-ray systems	Shanghai United Imaging Healthcare Co., Ltd....	https://www.accessdata.fda.gov/scr
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Spectral CT 7500	Philips Healthcare	https://www.accessdata.fda.gov/scr
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Electro mechanical medical devices

CareLink SmartSync Device Manager	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a
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Quantum PureFlow Standard Heat Exchanger High Flow	Spectrum Medical Ltd	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2216
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Medical Device	Manufacturer	Link
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Healthcare facility products and adaptations

MultiFiltratePRO	Fresenius Medical Care.	https://apps.tga.gov.au/Prod/DRAC/a
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Hospital hardware

Arjo Carevo shower trolley	Arjo Huntleigh	https://www.bfarm.de/SharedDocs/K
Arjo Carevo shower trolley	Arjo Huntleigh	https://apps.tga.gov.au/Prod/DRAC/a
PRO MRS SURFACE FOR VERSACARE	Baxter Healthcare	https://www.accessdata.fda.gov/scr

In vitro diagnostic devices

HemosIL AcuStar HIT-IgG (PF4-H)	Werfen..	https://apps.tga.gov.au/Prod/DRAC/a
SW-40 and SW-41 Rotors in Optima	Beckman Coulter...	https://apps.tga.gov.au/Prod/DRAC/a

Medical software

CareLink SmartSync Device Manager App	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a
Tandem t:slim mobile application	Tandem Diabetes Care, Inc	https://www.accessdata.fda.gov/scr

Non-active implantable devices

Embosphere Microspheres	Merit Medical Systems Inc....	https://www.accessdata.fda.gov/scr
Endo-Model Knee System - Centralizer Ø 12 mm - Implant	Waldemar Link GmbH & Co. KG	https://www.bfarm.de/SharedDocs/K
Pipeline Flex Embolization Device with Shield Technology, 3.00 mm x 20 mm 027	Micro Therapeutics Inc (DBA ev3 Neurovascular)	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2222
Ventilation (tympanostomy) Tube 5PK Button 1.27 FLPL	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a

Medical Device	Manufacturer	Link
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Reusable devices

EnCor EnCompass Breast Biopsy and Tissue Removal System Console	Bard Peripheral Vascular Inc.	https://www.accessdata.fda.gov/scr
Olympus M3 AutoClavable Telescope	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scr
TandemLoop Endoscopic Grasping Instrument	Ovesco Endoscopy AG.	https://www.bfarm.de/SharedDocs/K
Tripp-Lite P580-025 25ft DisplayPort Cable used in conjunction with OLYSENSE Hub System	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2217

Single-use devices

CitraLock Syringe 4%	Sterisets Medical Products.	https://www.bfarm.de/SharedDocs/K
Convenience kits containing BD Chloraprep Clear - 1 mL Applicator	Avid Medical, Inc.	https://www.accessdata.fda.gov/scr
Convenience kits containing BD Chloraprep Clear - 1 mL Applicator contaminated with Aspergillus penicillioides.	Avid Medical, Inc.	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=222426
Convenience Kits with Neurological Sponges	Medline Industries Inc	https://www.accessdata.fda.gov/scr
Ethilon Nylon Suture BLK 45CM 6-0 S/A P-1 PRM	Ethicon Inc.	https://apps.tga.gov.au/Prod/DRAC/a
hCG Pregnancy Test Strips	Alere San Diego.	https://www.accessdata.fda.gov/scr
Medical convenience kits containing BD CliniClean Pericare Wipes within BD Urinary Catheter Trays	American Contract Systems, Inc.	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2224

Medical Device	Manufacturer	Link
NDI Passive Spheres	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a
NYES Trinity Non-Surgical Isolation Gown	New York Embroidery Studio, Inc.	https://www.accessdata.fda.gov/scrip
Opportunity Pro, Flex and Performance Pro	American Nitrile Operations Llс	https://www.accessdata.fda.gov/scrip
Penumbra System (RED 62 Reperfusion Catheter)	Penumbra, Inc...	https://www.accessdata.fda.gov/scrip
Presource Packs, kits containing tube sets	Cardinal Health 200, LLC..	https://www.accessdata.fda.gov/scrip

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

