



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 10 dated 04/02/2026.

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. 10 / 2026

16 -08-1447 H

04 -02-2026

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 47

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
Pulsator Arterial Blood Sampling Kit Portex Spinal Tray	ICU Medical, Inc	https://www.accessdata.fda.gov/scr
Assistive products for persons with disability		
Molift Mover 205, Molift Mover 300, Molift 2-Punkt-Aufhängungen, Molift 4-Punkt-Aufhängungen	Etac Supply Center AB.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/02/2026/55214-
Dental devices		
Maxima Diamond Bur	Henry Schein, Inc...	https://www.bfarm.de/SharedDocs/K
NexxZr T Multi A.3.5 W98 -16 mm	Sagemax Bioceramics, Inc	https://www.bfarm.de/SharedDocs/K
Diagnostic and therapeutic radiation devices		
Azurion R4.0 Systems	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Azurion R4.0 Systems	Philips Healthcare	https://www.accessdata.fda.gov/scr
LEASEIR	LEASEIR TECHNOLOGIES SLU	https://www.accessdata.fda.gov/scr
mint Lesion	Mint Medical GmbH	https://www.bfarm.de/SharedDocs/K
PIXIUM PORTABLE 3543 EZ-C HD + PIXIUM PORTABLE 4343 EZ-C HD	THALES AVS FRANCE SAS	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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Electro mechanical medical devices

da Vinci SP, SP Access Port Kit	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scr
Grip Cable Failures on da Vinci S and Si Reusable Instruments with Jaws	Intuitive Surgical Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Mazor X robotic guidance system	Mazor Robotics	https://www.accessdata.fda.gov/scr
MEDLINE beds	Medline Industries Inc	https://www.accessdata.fda.gov/scr
Plum Duo Infusion Pump. Plum Solo Precision IV Pump.	ICU Medical, Inc	https://www.accessdata.fda.gov/scr
Plum Duo Infusion System.	ICU Medical, Inc	https://www.accessdata.fda.gov/scr
SIGMA Spectrum Infusion Pump.	Baxter Healthcare	https://www.accessdata.fda.gov/scr
Zimmer Tourniquet Systems	Zimmer Biomet	https://www.bfarm.de/SharedDocs/K

In vitro diagnostic devices

Alegria 2	ORGENTEC Diagnostika GmbH...	https://www.bfarm.de/SharedDocs/K
CentriMag Blood Pump	Abbott Medical ..	https://www.accessdata.fda.gov/scr
HemosIL SynthASil	Werfen..	https://www.accessdata.fda.gov/scr
Panocell® -20	Immucor GmbH.	https://ade.sfda.gov.sa/Fsca/PublishD
The LDL-Cholesterol assay	Beckman Coulter...	https://www.accessdata.fda.gov/scr
ThinPrep CytoLyt Solution. Buffered Cell Wash Solution.	Hologic Inc.	https://www.accessdata.fda.gov/scr
TS-10/TS-10H Tube Sorter	Sysmex Corporation	https://www.accessdata.fda.gov/scr



Medical Device

Manufacturer

Link

Medical software

Centricity Universal Viewer Zero Footprint Client (ZFP)	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
SynchroMed™ A810 Clinician Programmer Software Application v2.x.	Medtronic Inc.	https://www.bfarm.de/SharedDocs/K

Non-active implantable devices

- Endo-Model SL - Endo-Model Knee System - customLink	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2026/01289-
Orsiro	BIOTRONIK UK Ltd	https://www.bfarm.de/SharedDocs/K
Orthopaedic bone screw	Medartis AG.	https://www.bfarm.de/SharedDocs/K
TRIATHLON FIX. PEG 2 PER PK	Howmedica Osteonics Corp.	https://www.bfarm.de/SharedDocs/K
Trinity Cluster Shell 50mm Taper Size 3 and 46mm Taper Size 2	Corin Limited	https://apps.tga.gov.au/PROD/DRAC/
VOLT" Wrist Treatment System	Tyber Medical	https://www.accessdata.fda.gov/scr

Reusable devices

Cystoscope Outer sheath, 22.5 Fr.	Olympus Europa SE & CO.KG..	https://apps.tga.gov.au/PROD/DRAC/
da Vinci X and Xi Reusable Instruments with Jaws	Intuitive Surgical Inc	https://ade.sfda.gov.sa/Fsca/PublishD
HIPTURN FEM HEAD TRIAL 36MM REUSABLE	MicroPort Orthopedics Inc...	https://www.accessdata.fda.gov/scr
Tenaculum Forceps - Small Graptor on da Vinci X and Xi Tenaculum Forceps and Small Graptor	Intuitive Surgical Inc	https://ade.sfda.gov.sa/Fsca/PublishD etails/696



Medical Device	Manufacturer	Link
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Single-use devices

Alaris VP Infusion Sets	BD Switzerland Sarl	https://ade.sfda.gov.sa/Fsca/PublishD
Allurion Gastric Balloon System	Allurion technologies inc..	https://apps.tga.gov.au/PROD/DRAC/
Automated Compounding Device Inlet	Baxter Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
Brevera Breast Biopsy System Disposable 9 Gauge Needle	Hologic Inc	https://apps.tga.gov.au/PROD/DRAC/
Custom Waste Management Kit Vascular Tray Custom Procedure Kit Angiographic injector and syringe. Angioplasty Pack Custom Manifold Kit Custom Inflation Kit	Merit Medical Systems Inc....	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=217769
da Vinci S and Si Tenaculum Forceps and Permanent Cautery Hook	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishD
Infusionsbeutel Luerlock 100mL	SIV MEDICAL PRODUCTS IMPROMEDIFORM	https://www.bfarm.de/SharedDocs/K
Medline Kits containing Surgical Gowns, Packs, and Drapes	Medline Industries Inc	https://ade.sfda.gov.sa/Fsca/PublishDetails/710
PRISMAFLEX SETS, OXIRIS SETS	Baxter Healthcare	https://www.bfarm.de/SharedDocs/K
Tego Connector	ICU Medical, Inc	https://www.accessdata.fda.gov/scripts
ViziShot 2 FLEX (19G)	Olympus Corporation of the Americas .	https://ade.sfda.gov.sa/Fsca/PublishD



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.

**Act. Ph. Ibrahim Nasser Al Rashdi
Director General**

