Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

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 02 dated 13/01/2026.

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**

DSC مركز سلامة الدواء Drug Safety Center
ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Circular No. 02 / 2026

24 -07-1447 H

13 -01-2026

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 33

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
Myosa for Kids	Myofunctional Research Company USA	https://www.accessdata.fda.gov/scrip
NOxBOXi Nitric Oxide Delivery Device	NOxBOX Ltd.	https://www.bfarm.de/SharedDocs/K
Assistive products for persons with disability		
K Care Bass and Flinders Seat Walkers	K Care Pty Ltd	https://apps.tga.gov.au/PROD/DRAC/
Diagnostic and therapeutic radiation devices		
Omni Legend	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Allura Xper and Allura CV20 Systems	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
THUNDERBEAT Type S Hand Instruments	Olympus Corporation of the Americas .	https://apps.tga.gov.au/Prod/DRAC/a
Electro mechanical medical devices		
BD Alaris Syringe Pumps	BD Switzerland Sarl	https://ade.sfda.gov.sa/Fsca/PublishD
CellAED - Non-rechargeable public automated external defibrillator	RRR Manufacturing Pty Ltd	https://apps.tga.gov.au/PROD/DRAC/

Medical Device	Manufacturer	Link
Da Vinci 5	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scrip
Efficia DFM100 Defibrillator/Monitor	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishD
MADSEN ACCUSCREEN TEOAE/DPOAE/ABR Probe	PATH MEDICAL GmbH	https://www.accessdata.fda.gov/scrip
Mazor X Robotic Guidance System	Medtronic SA	https://apps.tga.gov.au/PROD/DRAC/
Stryker CranialMask Tracker	Howmedica Osteonics Corp.	https://www.accessdata.fda.gov/scrip
Hospital hardware		
BIOSURE REGENESORB (RG) 5×20 mm interference screw	Smith & Nephew inc	https://www.accessdata.fda.gov/scrip
In vitro diagnostic devices		
Alinity ci-series System Control Module (SCM).	Abbott	https://www.accessdata.fda.gov/scrip
Asserachrom HPIA	Diagnostica Stago S.A.S.	https://ade.sfda.gov.sa/Fsca/PublishD
cobas c 703 Analytical Unit	Roche Diagnostics GmbH.	https://www.bfarm.de/SharedDocs/K
TS-10	Sysmex Corporation	https://www.bfarm.de/SharedDocs/K
XN series Blood Bank mode	Sysmex Corporation	https://ade.sfda.gov.sa/Fsca/PublishD
Medical software		
Centricity RIS-i	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
InPen App	Medtronic MiniMed…	https://www.accessdata.fda.gov/scrip
LifeShield Infusion Safety Software Suite	ICU Medical, Inc	https://www.accessdata.fda.gov/scrip

Medical Device	Manufacturer	Link
LifeShield Infusion Safety Software Suite v2.2	ICU Medical, Inc	https://www.accessdata.fda.gov/scrip
Patient Information Center iX	Philips Medical Systems	https://ade.sfda.gov.sa/Fsca/PublishD
N/A		
BD Pyxis Medstation	CareFusion 303, Inc..	https://www.accessdata.fda.gov/scrip
Non-active implantable devices		
AART Malar Implant, AART Silicone Carving Implant, AART Calf Implant, AART Chin Implant, AART Gluteal Implant, AART Pectoral Implant	DSAART LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=216371
AXIOS Stent and Electrocautery Enhanced Delivery System	Boston Scientific Corp..	https://apps.tga.gov.au/Prod/DRAC/a
Single-use devices		
- CODMAN MICROSENSOR® Basic kit and - CERELINK®ICP sensor Basic kit	Integra LifeSciences Production Corporation	https://ade.sfda.gov.sa/Fsca/PublishDetails/674
AXIOS™ Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishD
da Vinci Single Port System Access Port Kits	Intuitive Surgical Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Damad-Prep Pad; Povidone-Iodine swabstick, 2 swabsticks /packet	The National Medical Products Co. Ltd. (Damad)	https://ade.sfda.gov.sa/Fsca/PublishD
Fine Round Diamond Bur 1.0MM and 1.5MM and 1.5MM	Stryker Instruments.	https://apps.tga.gov.au/PROD/DRAC/
Syringe 10ml L/L 3parts Red plunger	Molnlycke Health Care AB.	https://www.bfarm.de/SharedDocs/K

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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