



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 204 dated 17/11/2025.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



Circular No. 204 / 2025

26-05-1447 H

17-11-2025

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 48

Medical Device	Manufacturer	Link
Active Implantable Devices		
ACCOLADE Family of Pacemakers and CRT-Ps	Boston Scientific Corp..	https://www.accessdata.fda.gov/scr
Aeson® Total Artificial Heart	CARMAT SA..	https://www.bfarm.de/SharedDocs/K
AMS 700 Inflatable Penile Prosthesis	Boston Scientific Corp..	https://www.accessdata.fda.gov/scr
Automated Impella Controller (AIC)	ABIOMED Inc	https://www.accessdata.fda.gov/scr
Eterna™ SCS IPG	Abbott Medical ..	https://www.bfarm.de/SharedDocs/K
HeartMate II® and HeartMate 3™ System Controllers	Abbott Medical ..	https://ade.sfda.gov.sa/Fsca/PublishD
Anaesthetic and respiratory devices		
Airvo 2 - myAirvo 2	Fisher & Paykel Healthcare Limited	https://www.accessdata.fda.gov/scr
Ambu® SPUR® II	Ambu Inc	https://www.bfarm.de/SharedDocs/K
Medline Adult Anesthesia Set	Medline Industries Inc	https://www.accessdata.fda.gov/scr
V90 electronic vaporizer	szhen Mindray Bio-Medical Electronics Co., Lt	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device

Manufacturer

Link

Assistive products for persons with disability

ello V02 55G and ello_V02_62G	VOSS healthcare GmbH	https://www.bfarm.de/SharedDocs/K
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Diagnostic and therapeutic radiation devices

ARVIS" Shoulder	Kico Knee Innovation Company Pty Ltd	https://www.accessdata.fda.gov/scr
AZURION 7 M20	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
CT 5300 and Incisive CT	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Flex Focus, bkSpecto, bk3000, bk3500, bk5000, and bkActiv Ultrasound Systems with battery	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD etails/580
LOGIQ P9, LOGIQ P10 series with software version R4.5.7	GE Healthcare	https://www.accessdata.fda.gov/scr
Multiple MRI systems	Siemens Medical Solutions	https://www.bfarm.de/SharedDocs/K
Zenition 50 system	Philips Healthcare	https://www.bfarm.de/SharedDocs/K

Electro mechanical medical devices

Automated Impella Controller (AIC)	ABIOMED Inc	https://www.bfarm.de/SharedDocs/K
BD Alaris Syringe Pumps	BD Switzerland Sarl	https://ade.sfda.gov.sa/Fsca/PublishD
CADD-Solis Ambulatory Infusion Pumps	Smiths Medical..	https://apps.tga.gov.au/Prod/DRAC/a
CADD-Solis Ambulatory Infusion Pumps	Smiths Medical..	https://www.bfarm.de/SharedDocs/K
CentriMagTM Blood Pump	Abbott Medical ..	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device	Manufacturer	Link
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Exera III Colonovideoscope	Olympus Corporation of the Americas .	https://www.bfarm.de/SharedDocs/K
FERNO POWER X2 Powered Ambulance Cot	Ferno-Washington Inc	https://www.accessdata.fda.gov/scr
Patient Monitor 6500	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
XERF EFFECTOR 60	Lutronic Corporation...	https://www.accessdata.fda.gov/scr

In vitro diagnostic devices

Automated Digital Cell Morphology Analyzer DI-60	Sysmex Corporation	https://ade.sfda.gov.sa/Fsca/PublishD
Bartels ELISA Legionella Urinary Antigen	Trinity Biotech USA.	https://www.accessdata.fda.gov/scr
Bicarbonate	Beckman Coulter...	https://ade.sfda.gov.sa/Fsca/PublishD
Biosen Linearity Test Kit	EKF DIAGNOSTIC GmbH	https://www.bfarm.de/SharedDocs/K
FlexLab, FlexLab X System	Inpeco S.A.	https://www.accessdata.fda.gov/scr
IH-500	DiaMed GmbH.	https://apps.tga.gov.au/Prod/DRAC/a
MAS Omni CARDIO Liquid Assayed Integrated Cardiac Control	Microgenics Corp.	https://apps.tga.gov.au/PROD/DRAC/
Procalcitonin FS	DiaSys Diagnostic Systems GmbH...	https://www.bfarm.de/SharedDocs/K

Medical software

Omnipod 5 Automated Insulin Delivery System. Omnipod 5 iOS application.	Insulet Corporation.	https://www.accessdata.fda.gov/scr
ORBIS Medication 03.17.xx and higher	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K



Medical Device

Manufacturer

Link

Non-active implantable devices

Axonics Sacral Neuromodulation (SNM) System Tined Lead Kit	Axonics, Inc.	https://apps.tga.gov.au/PROD/DRAC/
Multiple devices	Biopro, Inc	https://www.accessdata.fda.gov/scr
Neuroguard IEP 3 in 1 Carotid Stent and PostDilation Balloon System with Integrated Embolic Protection	Contego Medical LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2158

Ophthalmic and optical devices

CRex, Cyclophen	Iantrek Inc.	https://www.accessdata.fda.gov/scr
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Single-use devices

W Gravity Burette Set	ICU Medical, Inc	https://apps.tga.gov.au/PROD/DRAC/
ECHELON LINEAR Cutters	Ethicon Inc.	https://www.accessdata.fda.gov/scr
Multiple devices	B Braun Medical Inc	https://www.accessdata.fda.gov/scr
Norse Rescue Chest Seal Vented Gauze	Wuxi Emsrun Technology Co., Ltd	https://www.bfarm.de/SharedDocs/K
NutraGlide Nasal Feeding Tube with Stylet and ENFit	Applied Medical Technology, Inc..	https://www.accessdata.fda.gov/scr
Phasitron 5 InLine Valve	Percussionaire Corporation	https://www.accessdata.fda.gov/scr
SD-400U-10 and SD-400U-15 Single Use Electrosurgical Snares	Olympus Corporation of the Americas .	https://apps.tga.gov.au/PROD/DRAC/



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**

