



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 206 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. **206** / 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 **52**

Medical Device	Manufacturer	Link
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Active Implantable Devices

Aurora EV-ICD™ (DVEA3E4), Clinical EV-ICD (DVEX3E4)	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/Publish
IsoSeed I25.S16	Eckert & Ziegler BEBIG GmbH	https://www.bfarm.de/SharedDocs/K

Anaesthetic and respiratory devices

A9 Anaesthesia System and V90 electronic vaporiser used with A9 Anaesthesia system	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.....	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-
AirICU	Feellife Health Inc.	https://www.bfarm.de/SharedDocs/K
ErgoStar CM 40, ErgoStar CM 45, ErgoStar CM 55, ErgoStar CM 60	Draeger Medical Systems Inc	https://ade.sfda.gov.sa/Fsca/Publish

Assistive products for persons with disability

Altair Lifting Solutions	Human Care HC Sweden AB	https://www.bfarm.de/SharedDocs/K
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Dental devices

Multi Unit Abutment	ALTATEC GmbH	https://www.bfarm.de/SharedDocs/K
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Medical Device	Manufacturer	Link
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Diagnostic and therapeutic radiation devices

Catalyst* HD, Catalyst HD	C-RAD Positioning AB	https://www.bfarm.de/SharedDocs/K
IMRIS Operating Suite	IMPRIS Imaging Inc	https://www.accessdata.fda.gov/scr
Incisive CT for Brazil SKD Incisive CT "CT 3500 "	Philips Healthcare	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216365
Millenium MG/MC	GE Healthcare	https://www.accessdata.fda.gov/scr
RadPRO ₆ Mobile 40kW; RadPRO ₆ Mobile 40kW FLEXPLUS Sedecal Easy Moving Plus AeroDR X30 MobileDiagnost wDR RadPRO ₆ Mobile 40kW Sedecal Easy Moving Plus	Sedecal S.A.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=214427
Surgical Theater	Surgical Theater Inc	https://www.accessdata.fda.gov/scr
VANTAGE GALAN 3T. CMSC	Canon Inc	https://www.accessdata.fda.gov/scr

Electro mechanical medical devices

BD Alaris System Pump (8100) & Bezel Spare Parts	CareFusion 303, Inc..	https://ade.sfda.gov.sa/Fsca/Publish
Cardiosave Hybrid	Getinge	https://ade.sfda.gov.sa/Fsca/Publish
CareLink™ Clinic	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/Publish
HeartSine Pad-Pak	HeartSine Technologies Ltd..	https://www.accessdata.fda.gov/scr



Medical Device	Manufacturer	Link
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Ivenix Infusion System	Fresenius Kabi	https://www.accessdata.fda.gov/scr
Oral Probe- Welch Allyn SureTemp Plus 690.	Welch Allyn, Inc	https://www.accessdata.fda.gov/scr
Sectra PACS (Sectra Core)	Sectra AB	https://apps.tga.gov.au/PROD/DRAC
t:slim X2 insulin pump with Interoperable Technology	Tandem Diabetes Care, Inc	https://www.accessdata.fda.gov/scr

In vitro diagnostic devices

Alethia Malaria	Meridian Bioscience Inc	https://apps.tga.gov.au/Prod/DRAC/
BD BACTEC™ Blood Culture System BD Phoenix™ M50 Automated Microbiology System BD MAX™ System BD COR™ System BD EpiCenter™ Microbiology Data Management System BD Synapsys™ Informatics Solution	Becton Dickinson & Co. (BD)	https://www.accessdata.fda.gov/scr https://www.accessdata.fda.gov/scr/centerfordevices/cdrh/cfdocs/cfRES/res.cfm?id=215731
CRP Reagent	Labor+ Technik	https://www.bfarm.de/SharedDocs/K
ELECTROLYTE ANALYZER W/O STARTERKIT 9180	Roche Diagnostics GmbH.	https://www.bfarm.de/SharedDocs/K
Greiner BIO-ONE VACUETTE 2 ml 9NC Coagulation sodium citrate 3.2%	Greiner Bio-One North America, Inc.	https://www.accessdata.fda.gov/scr
LIAISON C. difficile Toxins A&B Assay	DiaSorin Inc	https://apps.tga.gov.au/PROD/DRAC
NextSeq™ 550Dx sequencing reagent kits	Illumina Inc	https://ade.sfda.gov.sa/Fsca/Publish



Medical Device	Manufacturer	Link
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Laboratory equipment

RAM Scientific SAFETFILL Micro Capillary Blood Collection tubes	ASP Global, LLC. dba Anatomy Supply Partners, LLC.	https://www.accessdata.fda.gov/scr
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Medical software

CareLink Clinic	Medtronic Inc.	https://apps.tga.gov.au/PROD/DRAC
CGM CLINICAL Medication	CompuGroup Medical Deutschland AG	https://www.bfarm.de/SharedDocs/K
CGM CLINICAL Medication..	CompuGroup Medical Deutschland AG	https://www.bfarm.de/SharedDocs/K
EYESUITE MYOPIA for Lenstar	Haag-Streit AG	https://apps.tga.gov.au/PROD/DRAC
IntelePACS – InteleConnect / TechPortal	Intelrad Medical Systems Inc..	https://apps.tga.gov.au/PROD/DRAC
VIDAL Sécurisation	VIDAL France	https://www.bfarm.de/SharedDocs/K

Not related to a medical device

BD Pyxis MedFlex BD Pyxis CII Safe ES Tower Main BD Pyxis Pro MedStation Main BD Pyxis Pro 7-Drawer Auxiliary BD Pyxis Medbank	CareFusion 303, Inc..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=216046
Daye Coated Tampons	DAYE (ANNE'S DAY LTD)	https://www.accessdata.fda.gov/scr

Ophthalmic and optical devices

MST ArcDUO 9mm	MicroSurgical Technology, Inc.	https://www.accessdata.fda.gov/scr
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Medical Device	Manufacturer	Link
Single-use devices		
W Gravity Burette Set	ICU Medical, Inc	https://www.accessdata.fda.gov/scr
Alcon PRECISION1 One-Day Contact Lenses, -2.25D.	Alcon Laboratories Inc	https://www.accessdata.fda.gov/scr
Artegraft Collagen Vascular Graft	LeMaitre Vascular, Inc.	https://www.accessdata.fda.gov/scr
Basic Intravenous Administration Set	ICU Medical, Inc	https://apps.tga.gov.au/PROD/DRAC
Becker and Exacta external drainage and monitoring systems (EDMS).	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/Publish
Excelsior Medical, 0.9% Sodium Chloride Injection, USP - 10 mL Fill.	Medline Industries Inc	https://www.accessdata.fda.gov/scr
ExtremiLock Ankle 7 Hole Right Anterolateral Tibia Plate Sterile Qty 2	Acumed LLC,	https://www.bfarm.de/SharedDocs/K
Injekt Luer Solo	B. Braun Melsungen AG.	https://www.bfarm.de/SharedDocs/K
Magseed Pro	ENDOMAGNETICS LTD	https://www.accessdata.fda.gov/scr
Mega Ballast	Balt USA, LLC	https://www.accessdata.fda.gov/scr
Various Clear-Therm™ Mini HMEF	Intersurgical Limited	https://ade.sfda.gov.sa/Fsca/Publish
Various DART Intranasal Mucosal Atomization Devices	Pulmodyne Inc.	https://www.bfarm.de/SharedDocs/K
Various products including: ChemoLock, Clave Bag Spike w/ChemoLock Port, Oncology Kit, ChemosafeLock Vial Adapter	ICU Medical, Inc	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=216_155

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**

