



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 207 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. **207** / 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 **33**

Medical Device	Manufacturer	Link
Active Implantable Devices		
ACCOLADE Family of Pacemakers and CRT-Ps	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishD
Mi1250 SYNCHRONY 2	MED-EL Elektro-Medizinische Geraete GmbH	https://www.bfarm.de/SharedDocs/K
Anaesthetic and respiratory devices		
Clearway 2	BREAS Medical AB	https://www.bfarm.de/SharedDocs/K
SLE1500 & INTERFLOW GAS BLENDER	Inspiration Healthcare Limited	https://ade.sfda.gov.sa/Fsca/PublishD
Dental devices		
Inclusive Titanium Screw	Prismatik Dentalcraft, Inc	https://www.accessdata.fda.gov/scr
Diagnostic and therapeutic radiation devices		
Full Body UVB Therapy Unit	MEDlight GmbH	https://apps.tga.gov.au/Prod/DRAC/a
Osstem Dental X-Ray System T2, T2Plus, T1	OSSTEM Implant Co.	https://www.accessdata.fda.gov/scr
TruDi Navigation System	Integra LifeSciences	https://www.accessdata.fda.gov/scr



Medical Device

Manufacturer

Link

Zenition 10 & Zenition 30

Philips Medical Systems Nederland B.V.

<https://ade.sfda.gov.sa/Fsca/PublishD>

Electro mechanical medical devices

Corpuls3 Touch

S Elektromedizinische Geräte G. Stemple Gmb

<https://apps.tga.gov.au/PROD/DRAC/>

Giraffe OmniBed and Giraffe OmniBed
Carestation devices

Datex - Ohmeda Inc

<https://apps.tga.gov.au/PROD/DRAC/>

OER-AW ENDOSCOPE
REPROCESSOR

Olympus Corporation of the Americas .

<https://apps.tga.gov.au/Prod/DRAC/a>

Philips IntelliVue Patient Monitors

Philips Healthcare

<https://ade.sfda.gov.sa/Fsca/PublishD>

Tandem Mobi Insulin Pump

Tandem Diabetes Care, Inc

<https://www.accessdata.fda.gov/scr>

In vitro diagnostic devices

Access 2 Reaction Vessels

Beckman Coulter....

<https://ade.sfda.gov.sa/Fsca/PublishD>

Autocal

Gesellschaft für Biochemica und Diagnostic

<https://www.bfarm.de/SharedDocs/K>

BD BACTEC™ MGIT™ 960 PZA Kit

BD Biosciences

<https://ade.sfda.gov.sa/Fsca/PublishD>

Good Neighbor Pharmacy / TRUE
METRIX Self Monitoring Blood Glucose
Meter

Trividia Health

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2164>

Xpert CT/NG

Cepheid...

<https://ade.sfda.gov.sa/Fsca/PublishD>

Xpert SA Nasal Complete

Cepheid...

<https://www.accessdata.fda.gov/scr>

Medical software

CamAPS FX App und CamAPS and
mylife CamAPS

CamDiab ltd

<https://www.bfarm.de/SharedDocs/K>



Medical Device	Manufacturer	Link
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Dexcom G6 and G6 Pro Android US CGM App	DexCom Inc	https://www.accessdata.fda.gov/scr
Sentinel V11	Spacelabs Healthcare Inc	https://www.accessdata.fda.gov/scr

Non-active implantable devices

Klassic BiPolar Head	Total Joint Orthopedics, Inc.	https://www.accessdata.fda.gov/scr
LGN Tibial Offset Bushing 4MM	Smith & Nephew inc	https://ade.sfda.gov.sa/Fsca/PublishD

Single-use devices

CELOX PPH Uterine Haemostatic Tamponade	Medtrade products Ltd	https://www.bfarm.de/SharedDocs/K
CHEMOSAT Hepatic Delivery System	Delcath Systems	https://www.bfarm.de/SharedDocs/K
CODMAN® Disposable Perforator 11mm (26-1222) CODMAN® Disposable Perforator 9mm (26-1223)	Integra LifeSciences Production Corporation	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2161_25
Flocare Infinity III enteral feeding pump	Nutricia Medical Devices	https://apps.tga.gov.au/Prod/DRAC/a
KNEO THREADED FASTENING PINS	Groupe Lépine	https://ade.sfda.gov.sa/Fsca/PublishD
MAHURKAR" Acute High Pressure Triple Lumen Catheter Tray Curved Extensions with IC Components	Mozarc Medical US LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2167
Rocket Seldinger Chest Drain Kits	Rocket Medical	https://ade.sfda.gov.sa/Fsca/PublishD
Single Use Ligating Device PolyLoop	Olympus Europa SE & CO.KG..	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**

