



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 215 dated 15/12/2025.

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. 215 / 2025

24-06-1447 H

15-12-2025

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 20

Medical Device	Manufacturer	Link
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Assistive products for persons with disability

LISA LE therapy and nursing bed	FreiStil Tischlerei GmbH & Co. KG	https://www.bfarm.de/SharedDocs/K
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Diagnostic and therapeutic radiation devices

Digital Angiography System Trinitas - C-arm MH-600	Shimadzu Corporation.	https://apps.tga.gov.au/PROD/DRAC/
Digital Radiography X-ray System DR 800.	Agfa NV.	https://apps.tga.gov.au/PROD/DRAC/
SIGNA Prime	GE Healthcare.	https://www.bfarm.de/SharedDocs/K

Electro mechanical medical devices

Intracranial Pressure Monitor Pressio 2	Sophysa S.A.	https://apps.tga.gov.au/PROD/DRAC/
Ambulatory Elastomeric Infusion Pumps	Baxter Healthcare.	https://www.bfarm.de/SharedDocs/K
Cardiosave Hybrid	Geringe.	https://www.bfarm.de/SharedDocs/K
Infusomat Space Infusion Pump	B. Braun Melsungen AG.	https://apps.tga.gov.au/PROD/DRAC/
OTESUS OR table column	Geringe Disinfection AB.	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device

Manufacturer

Link

Sensis; Sensis Vibe Hemo; Sensis Vibe Combo; AXIOM Sensis Post processing WS; AXIOM Sensis Dedicated SIS Server with HP Flex Pro-C PCs used with the Sensis Vibe application

Siemens Healthcare GmbH.

<https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-01021-1>

Tempus Pro Monitor

Remote Diagnostic Technologies Ltd.

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

In vitro diagnostic devices

CleanCell M

Roche Diagnostics GmbH.

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

DiaClon Anti-P1

Bio-Rad.

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

MH Guide

Molecular Health GmbH.

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

Medical software

Æmatic Medical

Materialise N.V.

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

Vue PACS (Diagnostic) and Vue Motion version

Philips Healthcare.

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

Non-active implantable devices

Intracranial Pressure Monitor Pressio®2

Sophysa S.A.

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

Single-use devices

FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors

Abbott.

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

PALAMIX® uno

Heraeus Medical GmbH.

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

UNIMED Procedure Packs

United Medical Industries Co Ltd.

<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.

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

