

سلطنة غمسان 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 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





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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.

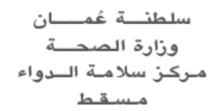
No. of Safety Alerts 20

Manufacturer	Link
s with disability	
FreiStil Tischlerei GmbH & Co. KG	https://www.bfarm.de/SharedDocs/K
diation devices	
Shimadzu Corporation.	https://apps.tga.gov.au/PROD/DRAC/
Agfa NV.	https://apps.tga.gov.au/PROD/DRAC/
GE Healthcare.	https://www.bfarm.de/SharedDocs/K
evices	
Sophysa S.A.	https://apps.tga.gov.au/PROD/DRAC/
Baxter Healthcare.	https://www.bfarm.de/SharedDocs/K
Getinge.	https://www.bfarm.de/SharedDocs/K
B. Braun Melsungen AG.	https://apps.tga.gov.au/PROD/DRAC/
Getinge Disinfection AB.	https://ade.sfda.gov.sa/Fsca/PublishD
	FreiStil Tischlerei GmbH & Co. KG diation devices Shimadzu Corporation. Agfa NV. GE Healthcare. evices Sophysa S.A. Baxter Healthcare. Getinge. B. Braun Melsungen AG.









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		
&matic 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 device	es	
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







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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





