

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 217 dated 22/12/2025.

#### Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- 1110
  - 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. 217 / 2025

02-07-1447 H

22-12-2025



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Attached below is the weekly report of Safety Alerts for Medical Devices. To identify the affected products and required action, please open the link.

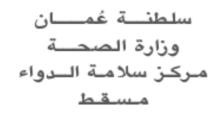
### No. of Safety Alerts 24

Medical Device	Manufacturer	Link
Active Implantable Devices		
Vanta Implantable Neurostimulator (INS)	Medtronic Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
Anaesthetic and respiratory of	levices	
SLE1500 & INTERFLOW GAS BLENDER	Inspiration Healthcare Limited	https://apps.tga.gov.au/Prod/DRAC/a
Diagnostic and therapeutic ra	adiation devices	
Head Fixation Device	IMIRIS imaging Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Azurion R2.1.10 and R2.2.10 Systems	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
Philips Azurion R3.1 Systems	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
Electro mechanical medical o	levices	
AGILIA SP TIVA	Fresenius Kabi	https://apps.tga.gov.au/PROD/DRAC/
AMSCO	STERIS Corporation	https://www.accessdata.fda.gov/scrip
Cardiosave Hybrid IABP Cardiosave Rescue	Datascope Corp	https://www.accessdata.fda.gov/scrip









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	المله عنصيان المناطقة	

Medical Device	Manufacturer	Link
Wiedicai Device	Manufacturer	Link
Cardiosave Hybrid IABP	Datascope Corp	https://www.accessdata.fda.gov/scrip
Cardiosave Rescue		
Hemodialysis System, Surdial DX	Nipro Corporation.	https://www.accessdata.fda.gov/scrip
Tomodaly 515 System, Surain 271	Tupre corporation.	integration with the control of the
Ivenix Infusion System (IIS)	Fresenius Kabi	https://www.accessdata.fda.gov/scrip
MV3 Bariatric Bed	Stryker Communications	https://www.accessdata.fda.gov/scrip
Arise 1000EX Mattress		
In vitro diagnostic devices		
TS-10	Sysmex Corporation	https://ade.sfda.gov.sa/Fsca/PublishD
Medical software		
	<b>51.1. 7</b>	
Leksell GammaPlan	Elekta Inc	https://ade.sfda.gov.sa/Fsca/PublishD
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
Non-active implantable dev	ices	
Trial Phantom Buttress	Enovis Corporation	https://www.bfarm.de/SharedDocs/K
Ophthalmic and optical dev	rices	
Photodynamic Therapy Device	Xuzhou Kernel Medical Equipment Co., Ltd.	https://www.bfarm.de/SharedDocs/K
Reusable devices		
Neusable devices		
HFD100 Torque Screw Assembly	Deerfield Imaging	https://www.bfarm.de/SharedDocs/K
<u> </u>		







## سلطنة غمان وزارة الصحة مركز سلامة الدواء مسقط

Medical Device	Manufacturer	Link		
Single-use devices	Moving Forward with Confidence			
Bard InLay Optima Ureteral Stent Kit	C.R. BARD	https://www.accessdata.fda.gov/scrip		
basixCOMPAK Inflation Device	Merit Medical Systems Inc	https://apps.tga.gov.au/Prod/DRAC/a		
ChemoPlus gowns	Cardinal Health 200, LLC	https://www.accessdata.fda.gov/scrip		
DEXLOCK Achilles Repair Implant Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip		
Quick Strip CURAD Fur Friends	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=217		
SCISSORS, OR, SHARP/BLUNT, 5.5", STERILE&ce related information	Medline Industries Inc	https://www.accessdata.fda.gov/scrip		





سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

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



