

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 190 dated 21/08/2025.

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





Moving Forward with Confidence

سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

Circular No. 190 / 2025

27-02-1447 H

21-08-2025

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 27

Medical Device	Manufacturer	Link		
Active Implantable Devices				
Canturio Smart Extension	Canary Medical, Inc.	https://www.accessdata.fda.gov/scrip		
Anaesthetic and respiratory device	es			
Ambu® SPUR® II	Ambu Inc	https://www.bfarm.de/SharedDocs/K		
Assistive products for persons wit	th disability			
Various Joystick	Mo-Vis BVBA	https://www.bfarm.de/SharedDocs/K		
Diagnostic and therapeutic radiat	ion devices			
Automated Impella Controller (AIC)	ABIOMED Inc	https://ade.sfda.gov.sa/Fsca/Publish		
Infinia Series and VG Series Nuclear Medicine systems	GE Healthcare	https://www.bfarm.de/SharedDocs/K		
Multiva 1.5T MR Systems	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/Publish		
Nellcor [™] Bedside SpO2 Patient Monitoring System	Covidien LLC	https://www.bfarm.de/SharedDocs/K		
O-arm O2 Imaging System.	Medtronic Navigation, Inc.	https://www.accessdata.fda.gov/scrip		







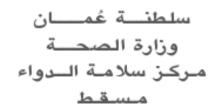
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Medical Device	Manufacturer	Link
Philips Allura R8.2.x System	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/Publish
X-ray High-Voltage Generator	Shimadzu Medical Systems	https://apps.tga.gov.au/Prod/DRAC/
Electro mechanical medical	devices	
da Vinci X and Xi Systems	Intuitive Surgical Inc	https://apps.tga.gov.au/Prod/DRAC/
Heater Unit HU 35	MAQUET Cardiopulmonary GmbH	https://ade.sfda.gov.sa/Fsca/Publish
Hugo TM Robotic-Assisted Surgery (RAS)	Medtronic Inc.	https://www.bfarm.de/SharedDocs/K
In vitro diagnostic devices		
Dexcom G6 OUS	DexCom Inc	https://apps.tga.gov.au/Prod/DRAC/
GETINGE CM320	Getinge Disinfection AB	https://apps.tga.gov.au/Prod/DRAC/
Liquid Urine Control Level 3	Randox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/Publish
QUANTA Flash® Centromere Controls	Werfen	https://ade.sfda.gov.sa/Fsca/Publish
Urinalysis Control Level 2	Randox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/Publish
VITEK 2 AST GN cards	bioMerieux Inc	https://apps.tga.gov.au/Prod/DRAC/
Non-active implantable dev	ices	
(Carotid WALLSTENT)	Boston Scientific Corp	https://www.bfarm.de/SharedDocs/K
POLYCENTRIC 4 BAR MANUAL LOCKING KNEE	Regal Prosthesis	https://www.bfarm.de/SharedDocs/K
Reusable devices		
Unity ASC femoral sizer	Corin Limited	https://www.bfarm.de/SharedDocs/K









Medical Device	Manufacturer	Link
Single-use devices		
BD Heyman Follower Straight Tip	C. R. Bard Inc.	https://www.accessdata.fda.gov/scrip
BD Vacutainer® Pronto™ Quick Release Needle Holder	Becton Dickinson & Co. (BD)	https://www.bfarm.de/SharedDocs/K
Blood Transfusion Set	Saudi Mais for Medical Products	https://ade.sfda.gov.sa/Fsca/Publish
Hummingbird	Neurovision Medical Products, Inc.	https://www.accessdata.fda.gov/scrip
lifecath CT PICC easy	Vygon UK Ltd	https://www.bfarm.de/SharedDocs/K

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.

Dr. Sharifa Amur Al Jabri Acting Director General





