



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 198 dated 07/10/2025.

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. 198 / 2025

14-04-1447 H

07-10-2025

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 28

Medical Device	Manufacturer	Link
Active Implantable Devices		
LivaNova's Model 1000 SenTiva™ and Model 1000-D SenTiva Duo™ VNS Therapy™ generators	LivaNova PLC	https://ade.sfda.gov.sa/Fsca/PublishDetails/281
Anaesthetic and respiratory devices		
A9 Anaesthesia System	zhen Mindray Bio-Medical Electronics Co., L	https://apps.tga.gov.au/PROD/D/RAC
Atlan anaesthesia workstations	Draeger Medical Systems Inc	https://www.accessdata.fda.gov/scrrip
Monnal T60 ventilator	Air Liquide Medical Systems S.A	https://apps.tga.gov.au/PROD/D/RAC
Dental devices		
IMPLANT EPIKUT PLUS	S.I.N. IMPLANT SYSTEM LTDA.,	https://www.accessdata.fda.gov/scrrip
Diagnostic and therapeutic radiation devices		
Digital Diagnostic Mobile X-ray System GM85	Samsung Electronics..	https://ade.sfda.gov.sa/Fsca/Publish
Medistim MiraQ Systems	Medistim ASA	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
ZAP-X Radiosurgery System,	Zap Surgical Systems..	https://www.accessdata.fda.gov/scrip

Electro mechanical medical devices

Automated Impella Controller (AIC)	ABIOMED Inc	https://ade.sfda.gov.sa/Fsca/Publications/Details/567
CARESCAPE B450, CARESCAPE ONE, B1x5M/B1x5P VSP3.0, B1x5M/B1x5P VSP4.0 Patient Monitors and Portrait Vital Signs Monitor	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publications/Details/567
HOTLINE HL-90 Blood & Fluid Warmer	Smiths Medical International Limited	https://www.bfarm.de/SharedDocs/K
Space plus Perfusor	B Braun Medical Inc	https://apps.tga.gov.au/PROD/DRAC
Venclose digiRF Generators	Bard Peripheral Vascular Inc.	https://www.accessdata.fda.gov/scrip

In vitro diagnostic devices

AlloSeq® cfDNA	careDx Pty Ltd...	https://ade.sfda.gov.sa/Fsca/Publications/Details/567
UniCel DxI 600 and 800 Analyzers	Beckman Coulter...	https://ade.sfda.gov.sa/Fsca/Publications/Details/567
VITEK 2 AST GN cards	bioMerieux Inc	https://www.accessdata.fda.gov/scrip



Medical Device

Manufacturer

Link

Laboratory equipment

Alinity hq Analyser	Abbott Laboratories Inc	https://ade.sfda.gov.sa/Fsca/Publicis
---------------------	-------------------------	---

ORTHO CONNECT	Biomedical Data Solutions Ltd.	https://ade.sfda.gov.sa/Fsca/Publicis
---------------	--------------------------------	---

Non-active implantable devices

EXETER V40 STEM	Howmedica Osteonics Corp.	https://www.accessdata.fda.gov/sc
-----------------	---------------------------	---

Reusable devices

JUNCTIONAL EMERGENCY TREATMENT TOOL (JETT)	North American Rescue	https://www.accessdata.fda.gov/sc
--	-----------------------	---

Leksell Vantage Arc System	Elekta Inc	https://ade.sfda.gov.sa/Fsca/Publicis
----------------------------	------------	---

STANDARD DRESSING FORCEPS 11,0CM	Tekno-Medical Optik Chirurgie GmbH..	https://www.bfarm.de/SharedDocs/K
----------------------------------	--------------------------------------	---

Vasoview Hemopro 3 Endoscopic Vessel Harvesting System	MAQUET Cardiovascular LLC.	https://www.accessdata.fda.gov/sc
--	----------------------------	---



Medical Device	Manufacturer	Link
Single-use devices		
CODMAN® Disposable Perforator 14mm and CODMAN® Craniotomy Kit containing Disposable Perforator 14mm	Integra LifeSciences Production Corporation	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/06/2025/45917-25_kundeninfo_en.pdf?blob=publi
IV Gravity Burette Set	ICU Medical, Inc	https://apps.tga.gov.au/PROD/DRAC
Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter, Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter, Medline ReNewal Reprocessed BW Webster CS Catheter with EZ Steer Technology; and Auto ID Technology, Medline ReNewal Reproces	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215768
Sterile Medline Convenience Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215768
VALVE PACK-LF	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215768



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**

