



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 192 dated 15/09/2025.

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. 192 / 2025

23-03-1447 H

15-09-2025

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
Anaesthetic and respiratory devices		
IPC Powerease System	Medtronic Inc.	https://www.accessdata.fda.gov/scr
Dental devices		
IO FLO-S Kit A04A and A04S	Dentsply Sirona, Inc	https://www.accessdata.fda.gov/scr
Diagnostic and therapeutic radiation devices		
Brilliance, Ingenuity, IQon Spectral CT	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
MAGNETOM Spectra, MAGNETOM Vida , MAGNETOM Lumina, MAGNETOM Cima.X , MAGNETOM Seara	Siemens Healthcare GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/520
OEC 9800, OEC 9900 Elite	GE Healthcare	https://www.accessdata.fda.gov/scr
Electro mechanical medical devices		
ICEfx™ Cryoablation System	Boston Scientific Corp.	https://www.bfarm.de/SharedDocs/K
MAC VU360 Acquisition Trunk Cable and Module Holder	GE Healthcare	https://ade.sfda.gov.sa/Fsca/Publish
SKULL TRACTION TONG LARGE	Aesculap AG	https://ade.sfda.gov.sa/Fsca/Publish



Medical Device	Manufacturer	Link
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Medrad Centargo CT Injection System	Imaxeon Pty Ltd	https://www.bfarm.de/SharedDocs/K
PrisMax Systems and TherMax Blood Warmer Units	Vantive Health GmbH	https://www.accessdata.fda.gov/scr
Spectrum IQ	Baxter Healthcare.	https://www.accessdata.fda.gov/scr
t:slim X2 Insulin Pump	Tandem Diabetes Care, Inc	https://www.accessdata.fda.gov/scr
Versius Surgeon Console	CMR Surgical Ltd	https://www.bfarm.de/SharedDocs/K

In vitro diagnostic devices

VIDAS FPSA	bioMerieux Inc	https://ade.sfda.gov.sa/Fsca/Publish
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Laboratory equipment

Dynex Agility Sample Tips	Dynex Technologies Inc.	https://www.accessdata.fda.gov/scr
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Non-active implantable devices

ELEOS BOWED CANAL FILLING STEMS	Onkos	https://www.accessdata.fda.gov/scr
Exactech Equinox Reverse Shoulder Humeral Liners	Exatech inc.	https://www.bfarm.de/SharedDocs/K
GORE ACUSEAL Vascular Graft	W.L. Gore & Associates Inc	https://www.bfarm.de/SharedDocs/K

Ophthalmic and optical devices

ViziShot 2 FLEX (19G)	Olympus Corporation of the Americas .	https://www.bfarm.de/SharedDocs/K
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Medical Device	Manufacturer	Link
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Reusable devices

Phantom Nose Pad Accessory Kit, Custom Dragonfly Loupes, Dragonfly Nose Pad Accessory Kit, Dragonfly Essential Kit, Phantom Loupes, Phantom Essential Kit,	Orasoptic.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215614
RAINBOW DCIP PED REUSABLE SENSOR & M-LNCS PED ADHESIVE SENSOR	Masimo Corporation	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-
THOR	THOR Photomedicine Ltd..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215614

Single-use devices

BD PhaSeal & BD PhaSeal Optima	Becton Dickinson & Co. (BD)	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215614
CleanLIFE Skin Cleansing Wipes Soft Pack	The Hygiene Co Pty Ltd	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-
Heartstring III Proximal Seal System	MAQUET Cardiovascular LLC.	https://www.bfarm.de/SharedDocs/K
Medline General Surgery Tray	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=215614
Op-Air One / FEELDRY – TIIR	MEDICOM SAS	https://www.bfarm.de/SharedDocs/K
Tentos 4F Stent System	optimed Medizinische Instrumente GmbH..	https://ade.sfda.gov.sa/Fsca/Publish



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**

