



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 203 dated 17/11/2025.

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. 203 / 2025

26-05-1447 H

17-11-2025

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 41

Medical Device	Manufacturer	Link
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Anaesthetic and respiratory devices

MEDAP TWISTA S. 1070, MEDAP BORA UP 2080, MEDAP VENTA S. 26 N, ATMOS Varioair 3 by ATMOS MedizinTechnik GmbH & Co. KGPDF, 284KB, File does not meet accessibility standards	ATMOS MedizinTechnik GmbH & Co. KG	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2025/46806-25_kundeninfo_en.pdf?blob=publicationFile
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NOxBOXi Nitric Oxide Delivery System	NOxBOX Ltd.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2160
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Dental devices

Ultramat S	SDI LTD.	https://apps.tga.gov.au/PROD/DRAC/
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Diagnostic and therapeutic radiation devices

Alphenix, INFX8000V/B, INFX8000V/S, V9.5, Alphenix, INFX8000C/B, INFX8000C/S, V9.2	Canon Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2160
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Ceiling Suspension Motorized (CSM) of Philips Diagnostic X-Ray (DXR) systems	Philips Medical Systems.	https://ade.sfda.gov.sa/Fsca/PublishDetails/571
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Change Healthcare Radiology Solutions software version 14.2.2	Change Healthcare.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2160
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Medical Device	Manufacturer	Link
ClariTEE Miniaturized TEE probe.	ImaCor Inc.	https://www.accessdata.fda.gov/scr
Siemens 3T MRI magnet systems (Verio) in IMRIS Operating Suites (iMRIS)	Deerfield Imaging.	https://apps.tga.gov.au/Prod/DRAC/a rn-detail.aspx?k=RC-2025-RN-00858-

Electro mechanical medical devices

AVVIGO+ Multi-Modality Guidance System	Boston Scientific Corp.	https://ade.sfda.gov.sa/Fsca/PublishD
BD Alaris Pump Infusion Sets	Becton Dickinson & Co. (BD).	https://www.accessdata.fda.gov/scr
CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes	Alcon Laboratories Inc.	https://www.bfarm.de/SharedDocs/K
Optiflux High Flux E-beam Dialyzer	Fresenius Medical Care.	https://www.accessdata.fda.gov/scr

In vitro diagnostic devices

- RX Daytona + with ISE - RX Daytona + without ISE - RX Imola - RX Modena	Randox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD etails/575
BD BACTEC™ Blood Culture System BD Phoenix™ M50 Automated Microbiology System BD MAX™ System BD COR™ System BD EpiCenter™ Microbiology Data Management System BD Synapsys™ Informatics Solution	Becton Dickinson & Co. (BD).	https://ade.sfda.gov.sa/Fsca/PublishD etails/172



Medical Device	Manufacturer	Link
BD BACTEC™ MGIT™ 960 Streptomycin 4.0 Kit	Becton Dickinson & Co. (BD).	https://ade.sfda.gov.sa/Fsca/PublishD
CD4 easy count kit, CD4% easy count kit	Sysmex Corporation.	https://www.bfarm.de/SharedDocs/K
CRP FS	DiaSys Diagnostic Systems GmbH.	https://www.bfarm.de/SharedDocs/K
Eschweiler combiline/Eschweiler modularPro	ESCHWEILER GmbH & Co. KG.	https://www.bfarm.de/SharedDocs/K
Evidence Investigator Analyser	Randox Laboratories Ltd.	https://apps.tga.gov.au/PROD/DRAC/
Evidence Investigator Analyser	Randox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD
IMMULITE IMMULITE 1000 IMMULITE 2000 IMMULITE 2000 Xpi	Siemens Healthcare Diagnostics Inc.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2025/46929-25_kundeninfo_en.pdf?blob=public
PakPlus	Immucor GmbH.	https://www.bfarm.de/SharedDocs/K
Perfect Control Cells	Diagnostic Grifols, S.A.	https://apps.tga.gov.au/PROD/DRAC/
ROTEM sigma complete	Tem Innovations GmbH.	https://apps.tga.gov.au/PROD/DRAC/
RX Monaco	Randox Laboratories Ltd.	https://ade.sfda.gov.sa/Fsca/PublishD
suPARnostic® TurbiLatex Reagents	ViroGates A/S.	https://www.bfarm.de/SharedDocs/K
SYNCHRON Systems Phosphorus (PHOSm) Reagent	Beckman Coulter.	https://www.accessdata.fda.gov/scr



Medical Device	Manufacturer	Link
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Medical software

IntelliSpace Cardiovascular	Philips Medical Systems Nederland B.V.	https://ade.sfda.gov.sa/Fsca/PublishD
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Non-active implantable devices

Artegraft Collagen Vascular Graft	LeMaitre Vascular, Inc.	https://www.accessdata.fda.gov/scr
Artegraft Collagen Vascular Grafts	LeMaitre Vascular, Inc.	https://www.accessdata.fda.gov/scr
Biosteon Screw	Biocomposites Ltd.	https://www.bfarm.de/SharedDocs/K
VITUS-Fi Distal Fibula Nail Ø 3.6mm, L 145mm	Dieter Marquardt-Medizintechnik GmbH.	https://www.bfarm.de/SharedDocs/K

Ophthalmic and optical devices

CorNeat EverPatch, EverPatch+	CORNEAT VISION, LTD.	https://www.accessdata.fda.gov/scr
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Single-use devices

Compoflow systems	Fresenius Kabi Ltd.	https://www.bfarm.de/SharedDocs/K
FreeGo Enteral Feeding set	Abbott Ireland Diagnostics Division.	https://ade.sfda.gov.sa/Fsca/PublishD
Medtronic, Simplera Sensor.	Medtronic Inc.	https://www.accessdata.fda.gov/scr
Natura +	ConvaTec.	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
NES Reprocessed 1.4mm OTW Turbo Elite Laser Atherectomy Catheter NES Reprocessed 0.9mm RX Turbo Elite Laser Atherectomy Catheter NES Reprocessed 0.9mm OTW Turbo Elite Laser Atherectomy Catheter NES Reprocessed 2.0mm OTW Turbo Elite Laser Atherectomy Ca	Northeast Scientific Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215846
Salem Sump™	Cardinal Health 200, LLC.	https://ade.sfda.gov.sa/Fsca/PublishD
Signia" Small Diameter Curved Tip Intelligent Reload	Covidien LLC.	https://www.bfarm.de/SharedDocs/K
Spectra Optia™ Apheresis System Bone Marrow Processing (BMP) Set	Terumo BCT Inc.	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.

**Ph. Ibrahim Nasser Al Rashdi
Director General**

