



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 85 dated 06/09/2026.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Department, DSC
- Director of Pharmacovigilance Department, DSC
- Director of Medicine Registration Department, DSC
- Director of Regulatory Compliance Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



Circular No. 85 / 2026

24 -03-1448 H

06 -09-2026

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 42

Medical Device	Manufacturer	Link
Anaesthetic and respiratory devices		
Rio" II Nasal Pillows Interface	3B Medical, Inc.	https://www.accessdata.fda.gov/scr
Assistive products for persons with disability		
M5 Corpus power wheelchairs	Permobil AB	https://apps.tga.gov.au/PROD/DRAC/
Munevo Drive, Drive R-Net	munevo GmbH	https://www.bfarm.de/SharedDocs/K
Complementary therapy devices		
Aquaflush Transanal Irrigation System	Clinisupplies(Nanjing) Co.,Ltd	https://www.bfarm.de/SharedDocs/K
Photera 600, 600 3-D, 400 phototherapy device	Daavlin Distributing Company	https://www.accessdata.fda.gov/scr
Diagnostic and therapeutic radiation devices		
Multiva 1.5T	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Electro mechanical medical devices		
Bubble Humidifier	HSINER CO., LTD.	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes	Alcon Laboratories Inc....	https://apps.tga.gov.au/Prod/DRAC/a
corpuls3 SLIM/SLIM TOUCH Defibrillator Module	GS Elektromedizinische Geräte G. Stemple GmbH	https://apps.tga.gov.au/Prod/DRAC/a
Da Vinci SP Instrument Arm Drape	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scr
Geringe Poladus 150 H1/H2	Geringe Disinfection AB	https://ade.sfda.gov.sa/Fsca/PublishD
ICU Medical Plum Duo Infusion Pump	ICU Medical, Inc	https://www.accessdata.fda.gov/scr
Oxygen Concentrator Kröber O2	Kröber Medizintechnik GmbH	https://www.bfarm.de/SharedDocs/K
The Vasoview Hemopro 2 Endoscopic Vessel Harvesting System	MAQUET Cardiopulmonary GmbH	https://www.accessdata.fda.gov/scr
Versius Surgical System US	CMR Surgical Ltd	https://www.accessdata.fda.gov/scr

In vitro diagnostic devices

Atellica CI Analyzer, Atellica IM Analyzer, ADVIA Centaur XP System & ADVIA Centaur XPT System	Siemens Healthcare Diagnostics GmbH	https://ade.sfda.gov.sa/Fsca/PublishDetails/891
cobas® b 123 Sensor Cartridge	Roche Diagnostics GmbH.	https://ade.sfda.gov.sa/Fsca/PublishD
DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter....	https://ade.sfda.gov.sa/Fsca/PublishD
DxC 500i Clinical Analyzer	Beckman Coulter....	https://ade.sfda.gov.sa/Fsca/PublishD
VITEK 2 AST-N447 TEST KIT	bioMérieux Inc	https://www.accessdata.fda.gov/scr



Medical Device	Manufacturer	Link
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Medical software

ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ORBIS Medication 84.43.04.00 and 84.43.02.00	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
SEMA	Schiller AG	https://www.bfarm.de/SharedDocs/K

Non-active implantable devices

B. Braun Aesculap Silver Graft® and Silver Graft® Helix vascular prostheses.	B Braun Surgical SA	https://ade.sfda.gov.sa/Fsca/PublishD
Endo-Model Knee System - Replacement Sets Tibial Plateaus	Waldemar LINK GmbH & Co	https://www.bfarm.de/SharedDocs/K

Reusable devices

Papapublic Replacement Brush Heads	Papapublic Inc	https://www.accessdata.fda.gov/scr
BESDATA Single Use Scope Console / Image Processor	Shenzhen Besdata Technology Co., Ltd...	https://apps.tga.gov.au/Prod/DRAC/a
Orthofix MINIRAIL, SHORT, LENGTHENER ARTICULATED MINIRAIL FIXATOR HORIZONTAL AXIS MINIRAIL, ARTICULATED, FIXATOR, VERTICAL AXIS MINIRAIL, STANDARD LENGTHENER	Orthofix	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221092
TMINI Femur Tracking Array, TMINI Tibia Tracking Array	Think Surgical, Inc.	https://www.accessdata.fda.gov/scr



Medical Device	Manufacturer	Link
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Single-use devices

3M Comply Lead Free Steam Indicator Tape	3M Health Care.....	https://ade.sfda.gov.sa/Fsca/PublishD
Abiomed Impella 14 Fr Introducer Kit, Abiomed Impella 23 Fr Introducer Kit	ABIOMED Inc	https://www.accessdata.fda.gov/scr
Angiodyn 3fold manifolds	B. Braun Melsungen	https://www.bfarm.de/SharedDocs/K
Argon Medical procedure kits	Argon Medical Devices, Inc...	https://www.accessdata.fda.gov/scr
Disposable Hemoperfusion Cartridge (HA Series)	Jafron Biomedical Co.,Ltd.	https://www.bfarm.de/SharedDocs/K
Ellik Evacuator Includes Glass Body, Male Connecting Tubing & Latex Bulb, Toomey Evacuator 30cc and 50cc with Adaptor, Glass Body for 194 Ellik Evacuator	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=220046
Endox A	Whiteley Corporation Pty Ltd.	https://apps.tga.gov.au/Prod/DRAC/a
Introducer Kit for Impella Hemostatic Peel Away Introducer System with Infusion Sideport	Oscor Inc....	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2208
Medline Convenience Kits containing all sizes of Medline Red Rubber Intermittent Catheters	Medline Industries Inc	https://ade.sfda.gov.sa/Fsca/PublishD etails/893
Medline Kits containing Zimmer Biomet mixing bowls and spatulas	Zimmer Biomet	https://www.accessdata.fda.gov/scr
Microbore Extension Sets and Lipid-Resistant Stop Cocks with Extension Sets (15 cm and 25 cm DEHP-Free)	BQ Plus Medical Co Ltd	https://apps.tga.gov.au/Prod/DRAC/a rn-detail.aspx?k=RC-2026-RN-00495-
St Neonatal PICC Pack and St Paediatric Angiography Pack	Multigate Medical Products. Pty Ltd.	https://apps.tga.gov.au/Prod/DRAC/a



ننقد بثقة
Moving Forward
with Confidence



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.

For

Ph. Ibrahim Nasser Al Rashdi
Director General

