



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 87 dated 10/09/2026.

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. 87 / 2026

28-03-1448 H

10-09-2026

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 44

Medical Device	Manufacturer	Link
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Anaesthetic and respiratory devices

Aisys CS2, Aisys CS2 with Et Control and S/5 Aisys Anesthesia Delivery Systems	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishDetails/913
Flow Anesthesia Machine: Flow-i C20 6677200 Flow-i C30 6677300 Flow-i C40 6677400 Flow-i C20 6888520 Flow-i C30 6888530 Flow-i C40 6888540 Flow-c 6887700 Flow-e 6887900	Maquet Critical Care AB	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221405

Complementary therapy devices

Charger for the Therabody Theragun, G4 PRO massage device	Therabody, Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221405
Nerivio Infinity	THERANICA BIOELECTRONICS LTD	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221405

Diagnostic and therapeutic radiation devices

Atellica CH Urine Albumin	Siemens Healthcare Diagnostics GmbH	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221405
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Medical Device	Manufacturer	Link
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MC2 Portable X-Ray System	Oxos Medical Inc	https://www.accessdata.fda.gov/scr
Philips Incisive CT System	Philips Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD

Electro mechanical medical devices

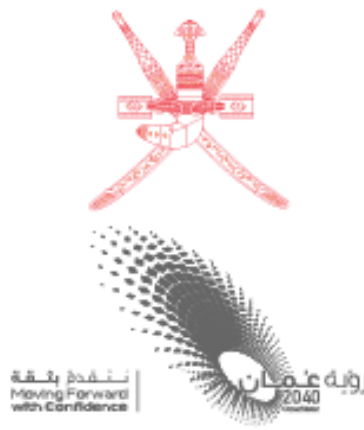
CERTOPIX PROTECT	B. BRAUN MEDICAL INC...	https://www.bfarm.de/SharedDocs/K
GE Healthcare MAC VU360	GE Healthcare	https://www.accessdata.fda.gov/scr
Mindray Monitors	hzen Mindray Bio-Medical Electronics Co., Lt	https://apps.tga.gov.au/Prod/DRAC/a
Philips Patient Information Center iX (PIC iX) 4.x systems	Philips Medizin Systeme GmbH	https://ade.sfda.gov.sa/Fsca/PublishD
STRYKER PKG, STRYKER AHTO TUBE SET PACKAGING, AHTO TUBE SET WITH TIP PACKAGING, AHTO DUAL SPIKE TUBE SET PACKAGING, STRYKEFLOW SUCTION/IRRIGATOR PS	Stryker Neurovascular...	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=221359

Healthcare facility products and adaptations

Carescape™ Central Station (CSCS) V3.0.x	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD
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In vitro diagnostic devices

HardyDisk AST Cefiderocol 30g (FDC30)	Hardy Diagnostics	https://www.accessdata.fda.gov/scr
210400 - ERYTRA	Diagnostic Grifols, S.A.	https://www.bfarm.de/SharedDocs/K
5-PLASMA	Aniara Diagnostica LLC	https://www.accessdata.fda.gov/scr
Aptiva CTD Essential Controls	INOVA Diagnostics, Inc.	https://www.bfarm.de/SharedDocs/K
cobas t 511 / t 711 coagulation analyzer	Roche Diagnostics GmbH.	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device	Manufacturer	Link
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CyFlow Counter	Sysmex Corporation	https://www.bfarm.de/SharedDocs/K
FilmArray NGDS Warrior Panel	BioFire Diagnostics Inc	https://www.accessdata.fda.gov/scr
Glycated Hemoglobin Analyzer	Goldsite Diagnostics Inc.	https://ade.sfda.gov.sa/Fsca/PublishD
GS1-HT Extraction Script for use within EasyScreen Sample Processing Kit Workflow	Genetic Signatures Ltd	https://apps.tga.gov.au/Prod/DRAC/a rn-detail.aspx?k=RC-2026-RN-00581-
MicroScan LabPro V5.03 Panel Update 11 DVD Kit (US). MicroScan LabPro V5.03 Panel Update 11 (US), Electronic.	Beckman Coulter UK Ltd	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfRES/res.cfm?id=221387
Syva Emit Disopyramide Assay	Siemens Healthcare Diagnostics GmbH	https://www.accessdata.fda.gov/scr

Medical software

Centricity Enterprise Archive, Enterprise Archive, Centricity PACS, and Centricity PACS Server	GE Healthcare	https://ade.sfda.gov.sa/Fsca/PublishD etails/912
GE Healthcare Portrait Core Services SW V 1.2.0, REF 5700592	GE Healthcare	https://www.accessdata.fda.gov/scr
Merge PACS, medical imaging diagnostic workstation	Merge Healthcare Corp	https://www.accessdata.fda.gov/scr
ORBIS Medication	DH Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
WASPLab	Copan WASP	https://www.accessdata.fda.gov/scr

Non-active implantable devices

Anti-Torque, Vector, Part: LS-749 part of Vector Pedicle Screw System	Innovasis, Inc	https://www.accessdata.fda.gov/scr
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Medical Device

Manufacturer

Link

GORE EXCLUDER Thoracoabdominal
Branch Endoprosthesis (TAMBE)

W.L. Gore & Associates Inc

<https://apps.tga.gov.au/Prod/DRAC/a>

U2 Total Knee System, USTAR II Knee
System

United Orthopedic Corporation

<https://www.accessdata.fda.gov/scr>

Ophthalmic and optical devices

Power Over Fiber Base Module

Terex Utilities

<https://www.accessdata.fda.gov/scr>

Reusable devices

Intramedullary Bone Saw

Zimmer Biomet

<https://www.accessdata.fda.gov/scr>

McGRATH MAC video laryngoscope

Aircraft Medical Limited

<https://apps.tga.gov.au/Prod/DRAC/a>

Pre-loved SNOO Smart Sleeper

Happiest Baby, Inc

<https://www.accessdata.fda.gov/scr>

Single-use devices

DASH Rapid PCR Instrument

Nuclein LLC

<https://www.accessdata.fda.gov/scr>

Dialysis Change Tray Clear Sequence

Medical Action Industries Inc.

<https://www.accessdata.fda.gov/scr>

DISPOSABLE SURGICAL GOWNS

Anhui MedPurest Medical Technology Co., Ltd

<https://ade.sfda.gov.sa/Fsca/PublishD>

Halyard convenience kits containing
recalled Medline Namic Angiographic
Star Off Handle Manifolds.

Avid Medical, Inc.

<https://www.accessdata.fda.gov/scr>
[ts/cdrh/cfdocs/cfres/res.cfm?id=2213](https://cdhrh/cfdocs/cfres/res.cfm?id=2213)

High Filtration Surgical Face Masks
with Ties Level 3

Med-Con Pty Ltd

<https://apps.tga.gov.au/Prod/DRAC/a>

Kingfisher Compact Individual First Aid
Kit, FORWARD Oral Airway Kit

INTEGRATED MEDCRAFT LLC

<https://www.accessdata.fda.gov/scr>



Medical Device	Manufacturer	Link
Pack Angiography NCMC 3/Cs BANNER, containing Medline Namic Angiographic Star Off Handle Manifolds	Medical Action Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221341
PIK 100 Insertion Kit, Guidewire 100 cm PIK 100-USA Insertion Kit Guidewire 100 PIK 150 Insertion Kit, Guidewire 150 cm PIK 150-USA Insertion Kit Guidewire 150 PIK dilator S PIK dilator set L	MAQUET Cardiopulmonary GmbH	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2026/34612-26_kundeninfo_en.pdf?__blob=publicationFile



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.

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

