



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 30 dated 16/03/2026.

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. 30 / 2026

26-09-1447 H

16-03-2026



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 52

Medical Device	Manufacturer	Link
<b>Anaesthetic and respiratory devices</b>		
HAMILTON-C2 with neonatal option	HAMILTON MEDICAL AG	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
AquaVENT® NeoFlow® nCPAP System, AquaVENT® NeoFlow® Humidified Oxygen System, AquaVENT® NeoFlow® Heated Ventilator Circuit	Armstrong Medical Ltd.	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/04662-26_kundeninfo_en.pdf?blob=publicationFile">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/04662-26_kundeninfo_en.pdf?blob=publicationFile</a>
Treadmill locomotion 150/50 DE med and locomotion 190/65 DE med	h/p/cosmos sports & medical gmbh.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
<b>Assistive products for persons with disability</b>		
Permobil M- & F- Corpus series models	Permobil AB	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
TRAM, E-Pacer	Community Products, LLC, d/b/a Rifton	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Dental devices</b>		
AQUASIL PUTTY - SOFT and HARD	DENTSPLY International	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
<b>Hospital hardware</b>		
TU2000 TRYTABLE	MEDKONSULT medical technology s.r.o..	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>



Medical Device	Manufacturer	Link
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### Medical software

Centricity Universal Viewer Software	GE Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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### Diagnostic and therapeutic radiation devices

Alphenix interventional fluoroscopic x- ray system	Canon Inc	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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LUMINOS Q.namix T, LUMINOS Q.namix R	Siemens Medical Solutions	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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MobileDiagnost wDR.	Philips Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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Philips Azurion Systems	Philips Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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Focalyx Fusion	Focalyx Technologies, LLC.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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Ingenia	Philips Medical Systems	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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Philips Allura and Azurion systems	Philips Healthcare	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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SOMATOM X.ceed	Siemens Healthcare GmbH	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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### Electro mechanical medical devices

BeneHeart C Series Automated External Defibrillator	Shenzhen Mindray Bio-Medical Electronics Co., Ltd...	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
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C-MAC 8403 range of Video Laryngoscopes	KARL STORZ SE & Co. KG.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
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Conductivity Standard Solution	Nipro Corporation.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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CS100 IABP CS300 IABP	Getinge	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
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Medical Device	Manufacturer	Link
EDAN	Edan Diagnostics	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
da Vinci X, Xi Surgical System, & da Vinci 5 Surgical System	Intuitive Surgical Inc	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
MiniMed 780G Insulin Pump	Medtronic MiniMed...	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
Olympus High Flow Insufflation Unit and UHI-3 INSUFFLATOR BUILT-IN SMOKE EVAC	Olympus Europa SE & CO.KG..	<a href="https://apps.tga.gov.au/Prod/DRAC/a-rn-detail.aspx?k=RC-2026-RN-00055-">https://apps.tga.gov.au/Prod/DRAC/a-rn-detail.aspx?k=RC-2026-RN-00055-</a>
Tentos 4F	optimed Medizinische Instrumente GmbH..	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>

#### In vitro diagnostic devices

Atellica CH Urinary/Cerebrospinal Fluid Protein	Siemens Healthcare Diagnostics GmbH	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
cobas HbA1c Test Gen. 2	Roche Diagnostics GmbH.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Xpert Carba-R	Cepheid...	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
COULTER DxH Diluent	Beckman Coulter...	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
Exploro Highly Sensitive Male Fertility / Sperm Concentration Test	Changchun Wancheng Bio-Electron Co., Ltd.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
GEM PAKs for GEM Premier 5000 with iQM2	Instrumentation Laboratory SpA, a Werfen Company	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
NucleoSpin® Dx Blood	Macherey Nagel GmbH & Co. Kg	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
STA LIATEST FREE PROTEIN S 6 and STA LIATEST FREE PROTEIN S 2	Diagnostica Stago	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>



Medical Device	Manufacturer	Link
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### Laboratory equipment

BECKMAN COULTER DxC 700 AU, BECKMAN COULTER Chemistry Analyzer AU5800	Beckman Coulter...	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/712">https://ade.sfda.gov.sa/Fsca/PublishDetails/712</a>
VITROS 4600 Chemistry System - VITROS 5600 Integrated System - VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	<a href="https://apps.tga.gov.au/Prod/DRAC/arn-detail.aspx?k=RC-2026-RN-00085-">https://apps.tga.gov.au/Prod/DRAC/arn-detail.aspx?k=RC-2026-RN-00085-</a>

### Non-active implantable devices

multiple devices	Aju Pharm Co.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
PearlMatrix" P15 Peptide Enhanced Bone Graft	Cerapedics, Inc..	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Sterile Silicone Breast Implants - Motiva Implant Matrix SilkSurface PLUS with Qid, Motiva Implant Matrix Ergonomix Round SilkSurface with Qid, and Truefixation SmoothSilk Sterile Silicone Breast Implants with Qid	Establishment Labs S.A..	<a href="https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00897-1">https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN-00897-1</a>
Drive Mechanism	OrthoPediatrics Corp	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
EMPOWR Dual Mobility	Encore Medical, L.P..	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Exactech Equinnox Reverse Total Shoulder Arthroplasty System	Exatech inc.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
TORNIER PERFORM REVERSED PERIP SCREW	Tornier Inc..	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>



Medical Device	Manufacturer	Link
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### Reusable devices

Cystoscope Outer sheath, 22.5 Fr.	Olympus Europa SE & CO.KG..	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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### Single-use devices

Ion Endoluminal System - Vision Probe Bag 10 pack	Intuitive Surgical Inc	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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Multiple devices	GOLD STAR DISTRIBUTION INC	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
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Paediatric arterial cannula	Andocor	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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SQ40S Blood Transfusion Filter	GVS TM, Inc	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
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Basic Endotracheal Tube	Multigate Medical Products. Pty Ltd.	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
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Darcofoam	Dr. Ausbüttel & Co. GmbH	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
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LimFlow Vector	LimFlow, Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
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LSL Healthcare, Central Line Dressing Kit	LSL Healthere Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
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MAJ-210 Single Biopsy Valve	Olympus Corporation of the Americas .	<a href="https://apps.tga.gov.au/Prod/DRAC/a">https://apps.tga.gov.au/Prod/DRAC/a</a>
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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**