



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 48 dated 11 /05/2026.

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. 48 / 2026

23 -11-1447 H

11-05-2026



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 35

Medical Device	Manufacturer	Link
<b>Active Implantable Devices</b>		
Automated Impella Controller (AIC)	ABIOMED Inc	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
HiResolution Bionic Ear System	Advanced Bionics Corp.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Assistive products for persons with disability</b>		
Aidacare Aspire Aura and Nova Lifters	Aidacare Pty Ltd	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Raz Mobile Shower Commode Chair	Raz Design Inc	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Diagnostic and therapeutic radiation devices</b>		
Philips Azurion and Allura Systems	Philips Medical Systems Nederland B.V.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
ProteusONE	Ion Beam Applications SA	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
RayStation	RaySearch Laboratories AB (publ)	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
RayStation/RayPlan 2024B	RaySearch Laboratories AB (publ)	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Refer to the FSN	RaySearch Laboratories AB (publ)	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Vue Motion V12	Philips Medical Systems Nederland B.V.	<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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### Electro mechanical medical devices

HealthCast "Vital Sync" Remote Patient Monitoring System	Covidien LLC...	<a href="https://www.accessdata.fda.gov/scrip">https://www.accessdata.fda.gov/scrip</a>
Philips IntelliVue Patient Monitors	Philips Healthcare	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
PHYSIO CONTROL INFANT/CHILD Reduced Energy Defibrillator Electrodes	Physio-Control, Inc.	<a href="https://www.accessdata.fda.gov/scrip">https://www.accessdata.fda.gov/scrip</a>
ShockPulse-SE Lithotripsy System	Olympus Corporation of the Americas .	<a href="https://www.accessdata.fda.gov/scrip">https://www.accessdata.fda.gov/scrip</a>
TRUE METRIX Blood Glucose Monitoring Systems	Trividia Health	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>

### Hospital hardware

- Lifetherm 2000 heated bed, height-adjustable - Lifetherm 2002 resuscitation unit - Lifetherm 2003 resuscitation unit	Lowenstein Medical GmbH &Co.KG	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/16/2026/09878-26_kundeninfo_en.pdf?__blob=public">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/16/2026/09878-26_kundeninfo_en.pdf?__blob=public</a>
Arjo Tenor Lift	Arjo Hospital Equipment AB	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>

### In vitro diagnostic devices

BD Kiestra™ ReadA	Becton Dickinson & Co. (BD)	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
STHEMO ANTI-Xa M STHEMO 201 STHEMO 301	Diagnostica Stago S.A.S.	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/08973-">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/08973-</a>
VITROS Chemistry Products Mg Slides	Ortho-Clinical Diagnostics	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>

### Laboratory equipment

BECKMAN COULTER DxC 700 AU, BECKMAN COULTER Chemistry Analyzer AU5800	Beckman Coulter...	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/05307-">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/05307-</a>
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Medical Device	Manufacturer	Link
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### Non-active implantable devices

Equinox, Equinox Ergo	Exactech	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
FLEXBAND	International Life Sciences	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>

### Reusable devices

Olympus PK, Everest, and Halo Cutting Forceps	Olympus Europa SE & CO.KG..	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Olympus PK, Everest, and Halo Cutting Forceps	Olympus Europa SE & CO.KG..	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>

### Single-use devices

- Approach® CTO-12 Micro Wire Guide - Blue Rhino® G2-Multi Percutaneous Tracheostomy Introducer Set - Cook Staged Extubation Set - NCompass® Nitinol Stone Extractor - Spectrum® Central Venous Catheter Set - Wayne Pneumothorax Set	Cook Incorporated	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/10800-26_kundeninfo_en.pdf?_blob=publicationFile">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2026/10800-26_kundeninfo_en.pdf?_blob=publicationFile</a>
21 Gauge Winged Infusion Sets from Specific Lots of CPX™ 4 Tissue Expanders	Mentor Worldwide LLC	<a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2026/09446-">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2026/09446-</a>
EndoVive Safety PEG Kit	Boston Scientific Corp..	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Luer-Lok Tip Syringe	Becton Dickinson & Co. (BD)	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>



Medical Device	Manufacturer	Link
MEDLINE UNNA-Z STRETCH ZINC PASTE BANDAGE	KOB GmbH	<a href="https://www.accessdata.fda.gov/scrip">https://www.accessdata.fda.gov/scrip</a>
Namic Compensator Manifolds	Medline Industries Inc	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
PowerLoc SWIS 20G x 1.9cm	Bard Access Systems.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Purge Cassette for Impella	ABIOMED Inc	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Various BVM Resuscitators	Intersurgical Limited	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Various procedure packs containing Namic Rotating Adaptor Syringes	Medline Industries Inc	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>



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

