



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 214 dated 15 /12/2025.

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. 214 / 2025

24 -06-1447 H

15 -12-2025

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 45

Medical Device	Manufacturer	Link
<b>Anaesthetic and respiratory devices</b>		
F120 Mobile ventilators	Fritz Stephan GmbH.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
V90 electronic vaporizer	Hzhen Mindray Bio-Medical Electronics Co., Lt	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Assistive products for persons with disability</b>		
DONJOY PERFORMANCE	DJO, LLC.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Klaxon Klick smart BMS batteries	KLAXON-Mobility GmbH	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
<b>Biologically-derived devices</b>		
SJM Pericardial Patch	Glycar S.A (Pty) Ltd.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Dental devices</b>		
Emdogain	Straumann USA, LLC	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
<b>Diagnostic and therapeutic radiation devices</b>		
InteleShare – ProViewer	Intelrad Medical Systems Inc.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Multiple MRI systems	Siemens Medical Solutions.	<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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Please refer to the attachment	BEBIG Medical GmbH.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
suiteHEART cMRI Analysis	Neosoft LLC.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
ViewPoint 6 Ultrasound Software	GE Healthcare.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>

### Electro mechanical medical devices

Galaxy System	Noah Medical.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
NICO Myriad Illumination Pack, NICO Myriad Handpiece, NICO BrainPath	Stryker Medical.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>
Quantum Intersegmental Table	Pivotal Health Solution, Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>

### Healthcare facility products and adaptations

Central Monitoring System (BeneVision / HYPERVISOR X)	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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### Hospital hardware

Accella therapy air mattresses (and spare parts associated with Progressa frames)	Hill Rom Inc.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/639">https://ade.sfda.gov.sa/Fsca/PublishDetails/639</a>
Laerdal Compact Suction Unit 4	Laerdal Medical AS.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>

### In vitro diagnostic devices

Alinity ci-series System Control Module (SCM).	Abbott.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/639">https://ade.sfda.gov.sa/Fsca/PublishDetails/639</a>
Bicarbonate	Beckman Coulter.	<a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/639">https://ade.sfda.gov.sa/Fsca/PublishDetails/639</a>
BioFire Respiratory Panel 2.1	BioFire Diagnostics Inc.	<a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>



Medical Device	Manufacturer	Link
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CAMHB, Brucella Broth	Remel Inc.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
FlexLab	Inpeco S.A.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
FlexLab	Inpeco S.A.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
FoundationOne Liquid CDx	Foundation Medicine, Inc..	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
GBM-Ab	Demeditec Diagnostics GmbH.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
UniCel DxI 600 and 800 Analyzers	Beckman Coulter.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Xpert MTB/RIF	Cepheid.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
Xpert® BCR-ABL Ultra	Cepheid.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>

### Laboratory equipment

LeadCare II Blood Lead Test Kit	Magellan Diagnostics Inc.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
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### Medical software

DermaSensor	DERMASENSOR INC.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
Mimics Medical	Materialise N.V.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>
Restore Clinician Programmer Application	Medtronic Inc.	<a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>

### Non-active implantable devices

Endo-Model Knee Fusion Nail SK	Waldemar LINK GmbH & Co.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Option"ELITE Vena Cava Filter System	Argon Medical Devices, Inc.	<a href="https://www.accessdata.fda.gov/scrrip">https://www.accessdata.fda.gov/scrrip</a>
Traumastem	Bioster, a.s.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>



Medical Device	Manufacturer	Link
<b>Reusable devices</b>		
Evis Exera III Duodenovideoscope. Evis Lucera Elite Duodenovideoscope. Duodenovideoscope.	Olympus Corporation of the Americas .	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2163">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2163</a>
<b>Single-use devices</b>		
3M Cavilon™ Durable Barrier Cream	3M Health Care.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
Central Venous Catheter Set (Double Lumen)	Saudi Mais for Medical Products.	<a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a>
EZDilate Nephrostomy Balloon Catheter and Inflation Device Kit	Olympus Corporation of the Americas .	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2163">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2163</a>
Flexor Check-Flo Introducers and Sets, Ring Transjugular Intrahepatic Access Sets, and Rosch-Uchida Transjugular Liver Access Sets	Cook Incorporated.	<a href="https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN- 00998-1">https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN- 00998-1</a>
Kimal Procedure Pac	Kimal plc.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>
Microstream Advance Neonatal-Infant and Adult-Pediatric Intubated CO2 Filter Line, Microstream Luer Adult- Pediatric Intubated CO2 Filter Line and Microstream Luer Adult-Pediatric Airway Adapter Sampling Line devices.	Draeger Medical Systems Inc.	<a href="https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN- 00966-1">https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2025-RN- 00966-1</a>
Multiple products	B Braun Medical Inc.	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2166">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2166</a>
Sterilmel Reprocessed Imaging Catheter, ACUSON, CATHETER ACUNAV DIAGNOSTIC ULTRASOUND	STERILMED, INC.	<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2166">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2166</a>
syringes	PAUL HARTMANN.	<a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</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**

