



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 197 dated 05/10/2025.

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. **197** / 2025

12-04-1447 H

05-10-2025

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 31**

| Medical Device                                        | Manufacturer                                | Link                                                                                      |
|-------------------------------------------------------|---------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Anaesthetic and respiratory devices</b>            |                                             |                                                                                           |
| Airvo 2 - myAirvo 2                                   | Fisher & Paykel Healthcare Limited.         | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |
| Inogen Rove 4 Portable Oxygen Concentrator            | Inogen, inc.                                | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |
| <b>Assistive products for persons with disability</b> |                                             |                                                                                           |
| Accella Therapy Air Mattresses                        | Hill Rom Inc.                               | <a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>       |
| <b>Dental devices</b>                                 |                                             |                                                                                           |
| GM Helix Implant 4.3x10.0 Acqua                       | Industria E Comercio De Materials Dentarios | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |
| <b>Diagnostic and therapeutic radiation devices</b>   |                                             |                                                                                           |
| Multiple MRI systems                                  | Siemens Medical Solutions.                  | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |
| Philips CT systems                                    | Philips Healthcare.                         | <a href="https://www.accessdata.fda.gov/scrip">https://www.accessdata.fda.gov/scrip</a>   |
| <b>Electro mechanical medical devices</b>             |                                             |                                                                                           |
| BD Alaris™ Pump Module 8100                           | CareFusion 303, Inc.                        | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> |
| C1/C3/C6/MR1/T1 OXYGEN SENSOR                         | Honeywell Healthcare Solutions GmbH.        | <a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>       |



| Medical Device                                            | Manufacturer                | Link                                                                                      |
|-----------------------------------------------------------|-----------------------------|-------------------------------------------------------------------------------------------|
| Carescape Central Station                                 | GE Healthcare.              | <a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>       |
| Chromophare Surgical Light System                         | Stryker Communications.     | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>       |
| CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes | Alcon Laboratories Inc.     | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> |
| HeartSine Pad-Pak                                         | HeartSine Technologies Ltd. | <a href="https://apps.tga.gov.au/PROD/DRAC/">https://apps.tga.gov.au/PROD/DRAC/</a>       |
| MADSEN AccuScreen<br>TEAOE/DPOAE/ABR Probe                | PATH MEDICAL GmbH.          | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |

### Healthcare facility products and adaptations

|                                         |                    |                                                                                     |
|-----------------------------------------|--------------------|-------------------------------------------------------------------------------------|
| handheld ultraviolet-C germicidal wand. | BigTree Sales Inc. | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a> |
|-----------------------------------------|--------------------|-------------------------------------------------------------------------------------|

### In vitro diagnostic devices

|                              |                          |                                                                                           |
|------------------------------|--------------------------|-------------------------------------------------------------------------------------------|
| DxC 500i Clinical Analyzer   | Beckman Coulter.         | <a href="https://ade.sfda.gov.sa/Fsca/PublishD">https://ade.sfda.gov.sa/Fsca/PublishD</a> |
| Erytra analyzer              | Diagnostic Grifols, S.A. | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>         |
| FilmArray NGDS Warrior Panel | BioFire Diagnostics Inc. | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>       |

### Medical software

|                                                                                            |                            |                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| t:slim X2 Insulin Pump with<br>Interoperable Technology (with Tandem<br>t:slim mobile app) | Tandem Diabetes Care, Inc. | <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2150">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2150</a> |
|--------------------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Non-active implantable devices

|                                                                                                     |                      |                                                                                                                                                                                                                             |
|-----------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| - FRED™ 27 Flow Re-Direction<br>Endoluminal Device<br>- FRED™ X 27 Flow Re-Direction<br>Endoluminal | MicroVention Europe. | <a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2025/44793-25_kundeninfo_en.pdf?blob=publicationFile">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/11/2025/44793-25_kundeninfo_en.pdf?blob=publicationFile</a> |
|-----------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



| Medical Device                                                                                                        | Manufacturer             | Link                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Catalyft PL Expandable Interbody System                                                                               | Medtronic SA.            | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>                                                                                                                                           |
| Juggerknot Mini Soft Anchors                                                                                          | Biomet Sport Medicine.   | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>                                                                                                                                         |
| Ortoma Inserter Adapter OTD                                                                                           | ORTOMA AB.               | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>                                                                                                                                         |
| OSSURETM Local Osteo-Enhancement Procedure (LOEP) Kit.                                                                | AgNovos Healthcare.      | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>                                                                                                                                           |
| ZENITH ALPHA® 2 THORACIC ENDOVASCULAR GRAFT                                                                           | Wilson-Cook Medical Inc. | <a href="https://www.bfarm.de/SharedDocs/K">https://www.bfarm.de/SharedDocs/K</a>                                                                                                                                           |
| - UROMED Silicone Balloon Catheter "INTEGRAL"<br>- UROMED >>PROSIL<< DBK COUVELAIRE<br>- UROMED-SUPRA-KATH-"INTEGRAL" | UROMED Kurt Drews KG.    | <a href="https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/45261-25_kundeninfo_en.pdf?blob=publicationFile">https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2025/45261-25_kundeninfo_en.pdf?blob=publicationFile</a> |
| 3M Ranger Blood/Fluid Warming High Flow Set                                                                           | 3M Health Care.          | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>                                                                                                                                         |
| ContinuFlo Solution Set                                                                                               | Baxter Healthcare.       | <a href="https://www.accessdata.fda.gov/scr">https://www.accessdata.fda.gov/scr</a>                                                                                                                                         |
| Medline Kits containing Flexicare BritePro Solo Fiber Optic Laryngoscope Handles.                                     | Medline Industries Inc.  | <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215</a>                                                               |
| Sofmed Breathables MyDay Toric Voyant 1-Day Premium Toric                                                             | CooperVision Inc.        | <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215</a>                                                               |
| STRATAFIX Spiral PDS Plus Bidirectional Knotless Tissue Control Device.                                               | Ethicon Inc.             | <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215</a>                                                               |
| SureStep Foley Tray System Bardex I.C. Complete Care Infection Control Foley Catheter Tray.                           | C.R. BARD.               | <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=215</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**

