وزارة الصحة
Ministry of Health
Sultanate of Oman سلطنة عمان

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 112 dated 09/11/2026.

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. 112 / 2026

29-05-1448 H

09-11-2026

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 53

Medical Device	Manufacturer	Link
Active Implantable Devices		
Evoke Closed Loop Stimulator (CLS)	SALUDA MEDICAL PTY LTD	https://apps.tga.gov.au/Prod/DRAC/a
Anaesthetic and respiratory devices		
Rotaflow Console	MAQUET Cardiopulmonary GmbH	https://www.bfarm.de/SharedDocs/K
VOCSN+ PRO Devices	Ventec Life Systems, Inc..	https://www.accessdata.fda.gov/scrip
Dental devices		
TENAX FIBER TRANS Translucent Esthetic Post System	Coltene Whaledent Inc.	https://www.bfarm.de/SharedDocs/K
Diagnostic and therapeutic radiation devices		
Horizon-WI Dual-Energy X-ray Absorptiometry (DXA) System	Hologic Inc	https://apps.tga.gov.au/Prod/DRAC/a
Xact mole marker for mammography	Solstice Corporation	https://www.accessdata.fda.gov/scrip
ARTIS icono / pheno system with version VE50B	Siemens Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
ARTIS pheno, ARTIS icono floor, ARTIS icono biplane, ARTIS icono ceiling	Siemens Healthcare GmbH	https://www.bfarm.de/SharedDocs/K
OptiCross Intravascular Ultrasound (IVUS) Imaging Catheters	Boston Scientific Corp..	https://www.bfarm.de/SharedDocs/K
Scout MD Delivery System	Merit Medical Systems Inc....	https://www.accessdata.fda.gov/scrip

Medical Device	Manufacturer	Link
Electro mechanical medical devices		
6008 CAREsystem	Fresenius Medical Care.	https://apps.tga.gov.au/Prod/DRAC/a
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE	Olympus Corporation of the Americas .	https://apps.tga.gov.au/Prod/DRAC/a
Ion Torrent Genexus Dx with software	Life Technologies Limited.	https://www.accessdata.fda.gov/scrip
OmniaSecure Model 3930M	Medtronic Inc.	https://www.accessdata.fda.gov/scrip
Syriflow MR infusion pump	MEDTRON AG	https://www.bfarm.de/SharedDocs/K
HeartSine samaritan PAD	HeartSine Technologies Ltd..	https://www.bfarm.de/SharedDocs/K
HF (high-frequency) bipolar cable	Olympus Corporation of the Americas .	https://apps.tga.gov.au/Prod/DRAC/a
MiniMed™ Paradigm™, MiniMed™ 600 series, and MiniMed™ 700 series insulin pump systems	Medtronic MiniMed...	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2026/02838-
Philips Smart-hopping	Philips Healthcare	https://www.accessdata.fda.gov/scrip
Hospital hardware		
Medifa 7000 Operating Tables	medifa GmbH	https://www.bfarm.de/SharedDocs/K
TruSystem 7000 and TruSystem 7500	Baxter Healthcare	https://apps.tga.gov.au/Prod/DRAC/a
In vitro diagnostic devices		
ARCHITECT i2000SR	Abbott Laboratories Inc	https://www.bfarm.de/SharedDocs/K
ABL90 FLEX and ABL90 FLEX PLUS analyzer	Radiometer Medical ApS	https://www.accessdata.fda.gov/scrip
PD-L1 IHC 22C3 pharmDx.	Agilent Technologies, Inc.	https://apps.tga.gov.au/Prod/DRAC/a
Applied Biosystems Diomni Software	Life Technologies Limited.	https://www.bfarm.de/SharedDocs/K
EMAG system	bioMerieux Inc	https://www.accessdata.fda.gov/scrip
Euroimmun IIFT: Legionella Mosaic 7 (IgAGM)	EUROIMMUN Medizinische Labordiagnostika AG	https://apps.tga.gov.au/Prod/DRAC/a
VACUETTE LH Lithium Heparin Separator	Greiner Bio-One North America, Inc.	https://www.accessdata.fda.gov/scrip

Medical Device	Manufacturer	Link
Medical software		
Abbotts Libre App	Abbott	https://apps.tga.gov.au/Prod/DRAC/a
CareLink Clinic Software Version 4.4A	Medtronic Inc.	https://www.accessdata.fda.gov/scrip
Reusable devices		
Think Surgical Square Driver	Think Surgical, Inc.	https://www.accessdata.fda.gov/scrip
Unity ASC Modular Handle	Corin Limited	https://www.bfarm.de/SharedDocs/K
Non-active implantable devices		
aerstent TBY	bess pro gmbh	https://www.bfarm.de/SharedDocs/K
GrapplerR3FLEX Stabilization System Kits	Paragon 28, Inc..	https://apps.tga.gov.au/Prod/DRAC/a
restor3d MTP Implant	restor3d Inc.	https://www.accessdata.fda.gov/scrip
Ophthalmic and optical devices		
Softmed Breathables Advanced Toric Contact Lens	CooperVision Inc...	https://www.accessdata.fda.gov/scrip
Single-use devices		
Convenience Kits containing cannula components	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
Convenience Kits containing CONMED AirSeal Access Ports	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
InterPulse® System products	Stryker Instruments.	https://www.bfarm.de/SharedDocs/K
Medline convenience kit labeled as: FOOT ANKLE	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
PNE Lead Implant Kit	Axonics, Inc.	https://www.accessdata.fda.gov/scrip
Steriflush Syringes with water containing 10% glycerine	Sterisets International B.V.	https://www.bfarm.de/SharedDocs/K
Direxion, Direxion Hi-Flo	Boston Scientific Corp..	https://www.accessdata.fda.gov/scrip
ES2® Spinal System Nitinol K-Wire Blunt	Stryker Spine.	https://www.bfarm.de/SharedDocs/K

Medical Device	Manufacturer	Link
ESENTA Stomahesive Paste	ConvaTec	https://www.bfarm.de/SharedDocs/K
Halyard ANTERIOR HIP PACK	Avid Medical, Inc.	https://www.accessdata.fda.gov/scrip
Medical convenience kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
SAFE-T-CENTESIS KITS	Bard Peripheral Vascular Inc.	https://apps.tga.gov.au/Prod/DRAC/a
Schiffa Skin Lesion Kit SCP100 & SCP111	Jiangsu Yada Technology Group Ltd	https://apps.tga.gov.au/Prod/DRAC/a
SOLTIVE Single-use Laser Fibers	Gyrus ACMI, Inc.	https://www.bfarm.de/SharedDocs/K
Steriflush Syringes with water	Sterisets International B.V.	https://www.bfarm.de/SharedDocs/K
Uterine Curettes	KLS Martin GmbH + Co. KG	https://apps.tga.gov.au/Prod/DRAC/a
TS Femoral Prep Tray,TS Universal Baseplate Finishing Tray, Triathlon Hinge Femoral Prep Tray	Howmedica Osteonics Corp.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2228

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

سلطنة عمان - وزارة الصحة
مركز سلامة الدواء
DRUG SAFETY CENTER
SULTANATE OF OMAN - MINISTRY OF HEALTH
1