



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 59 dated 21/06/2026.

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. 59 / 2026

06-12-1447 H

21-06-2026



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 59

Medical Device	Manufacturer	Link
Active Implantable Devices		
ACCOLADE Family of Pacemakers and CRT-Ps	Boston Scientific Corp..	https://ade.sfda.gov.sa/Fsca/PublishD
Anaesthetic and respiratory devices		
Blue Ventilator Adapter Module	Hill Rom Inc	https://www.accessdata.fda.gov/scr
Dental devices		
Adhese 2 DC VivaPen Kits and DC Cannulas for VivaPen	Ivoclar Vivadent AG..	https://apps.tga.gov.au/PROD/DRAC/
Jiffy Original Composite Polisher Cups (Coarse) 12pk	ultradent products INC.	https://www.accessdata.fda.gov/scr
Straumann Custom Abutments, P.004 RC CARES TITANIUM AND CERAMIC ABUTMENTS	Straumann Manufacturing, Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=2190



Medical Device	Manufacturer	Link
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Diagnostic and therapeutic radiation devices

ARTIS pheno	Siemens Healthcare GmbH	https://apps.tga.gov.au/PROD/DRAC/
eTRAX Needle System Starter Kit 12G eTRAX Needle Sensor - 14G eTRAX Needle Sensor - 12G eTRAX Needle Sensor - 18G eTRAX Needle System Starter Kit 16G eTRAX Needle Sensor - 16G eTRAX Needle System Starter Kit 14G eTRAX Needle System Starter Kit 18G	CIVCO Medical Instruments Co., Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218963
Mobile x-ray System	Micro-X Ltd	https://apps.tga.gov.au/PROD/DRAC/
Philips IQon, iCT, Ingenuity, and Brilliance CT 64 systems	Philips Medical Systems	https://apps.tga.gov.au/PROD/DRAC/
RefleXion X1 Radiotherapy System	Reflexion Medical, Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218963
SIGNA Premier	GE Healthcare	https://www.bfarm.de/SharedDocs/K

Electro mechanical medical devices

Alaris™ Point-of-Care Unit (PCU) & BD Alaris™ Point-of-Care Unit (PCU)	CareFusion 303, Inc..	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218963
Alaris™ Point-of-Care Unit (PCU) & BD Alaris™ Point-of-Care Unit (PCU)	CareFusion 303, Inc..	https://ade.sfda.gov.sa/Fsca/PublishD
BiDop 3	Koven Technology, Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218963
CHROMOPHARE Softlit Ring Surgical Light System	Stryker Communications.....	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218963



Medical Device	Manufacturer	Link
CONSTELLATION® ULTRAVIT® (10K) and HYPERVIT® (20K) probes	Alcon Laboratories Inc...	https://ade.sfda.gov.sa/Fsca/PublishD
corpuls3 Product-family with Glasgow Full Scale or HES-License	GS Elektromedizinische Geräte G. Stemple GmbH	https://ade.sfda.gov.sa/Fsca/PublishD
Endoscope Reprocessor OERElite, Endoscope Suction Valve MAJ1443, Endoscope Reprocessor OERPro, Endoscope Air/Water Valve MAJ1444	Olympus Corporation of the Americas .	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
Giraffe and Panda warmer with Integrated Resuscitation System (iRes) and Giraffe Stand-alone Infant Resuscitation System	Datex - Ohmeda Inc	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2026-RN-00236-1
Grip Cable Failures on da Vinci S and Si Reusable Instruments with Jaws	Intuitive Surgical Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
Handy Solutions Heating Pad Neck and Shoulders	Navajo Manufacturing Company	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
LINK Embrace Shoulder System	Waldemar Link GmbH & Co. KG	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
M ZN-AIR BATTERY PAK	Advanced Bionics Corp.	https://ade.sfda.gov.sa/Fsca/PublishD
Multi-parameter Command Module	Spacelabs Healthcare Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Paradise Catheter for Paradise Ultrasound Renal Denervation System.	ReCor Medical Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
t:slim X2 Insulin Pump	Tandem Diabetes Care, Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=218481
Hospital hardware		
Getinge Steam Sterilizers	Getinge Sterilization AB	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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In vitro diagnostic devices

- Atellica CI Analyzer - Atellica IM Analyzer - ADVIA Centaur XP System - ADVIA Centaur XPT System - ADVIA Centaur CP System	Siemens Healthcare Diagnostics Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/11107-26_kundeninfo_en.pdf? blob=publicationFile
- IMMULITE 2000 - IMMULITE 2000 Xpi	Siemens Healthcare Diagnostics Inc.	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/11107-26_kundeninfo_en.pdf? blob=publicationFile
Atellica CH Analyzer Atellica CI Analyzer	Siemens Healthcare Diagnostics GmbH	https://ade.sfda.gov.sa/Fsca/PublishD
BD Kiestra™ ReadA	Becton Dickinson & Co. (BD)	https://www.accessdata.fda.gov/scr
Dexcom ONE+ iOS App Dexcom G7 iOS / G7 Watch iOS App	DexCom Inc	https://ade.sfda.gov.sa/Fsca/PublishD
Dimension Clinical Chemistry System	Siemens Healthcare Diagnostics Inc	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/11107-26_kundeninfo_en.pdf? blob=publicationFile
HemosIL SynthAFax	Werfen..	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/11107-26_kundeninfo_en.pdf? blob=publicationFile
MicroScan Neg MIC 56	Beckman Coulter Inc..	https://www.accessdata.fda.gov/scr
OXOID Agglutinating Sera, Salmonella 9-O	Remel Inc.	https://ade.sfda.gov.sa/Fsca/PublishD

Medical software

INFINITT PACS 7.0	INFINITT Europe GmbH	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/08/2026/11107-26_kundeninfo_en.pdf? blob=publicationFile
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Non-active implantable devices

Drill Plate	Orthalign, Inc	https://www.accessdata.fda.gov/scr
EVOQUE Tricuspid Delivery System	Edwards Lifesciences	https://ade.sfda.gov.sa/Fsca/PublishD



Medical Device	Manufacturer	Link
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MENTOR CPX 4 US Breast Tissue Expanders with Suture Tabs ARTOURA Breast Tissue Expanders Mentor CPX 4 US Breast Tissues Expanders with Suture Tabs	Mentor Worldwide LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218887
Movita Breast Implants	Establishment Labs S.A..	https://apps.tga.gov.au/PROD/DRAC/
Patient-Fitted Temporomandibular Joint (TMJ) Reconstruction Prosthesis	Stryker Leibinger GmbH & Co.KG	https://apps.tga.gov.au/PROD/DRAC/
PROXIMAL STRAIGHT HUMERAL NAIL 8/7 X 16	Smith & Nephew inc	https://www.bfarm.de/SharedDocs/K
SX-ELLA Stent Danis (Danis Stent), Danis Procedure Pack – Basic, Danis Procedure Pack	ELLA-CS, s.r.o.	https://ade.sfda.gov.sa/Fsca/PublishDetails/769

Ophthalmic and optical devices

TECNIS Eyhance IOL with TECNIS Simplicity" Delivery System	Johnson & Johnson Surgical Vision, Inc.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218887
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Reusable devices

Intra uterine tube with 4 mm diameter	Nucletron bv	https://apps.tga.gov.au/PROD/DRAC/
MiniMed 780G	Medtronic MiniMed...	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218887



Medical Device	Manufacturer	Link
Single-use devices		
1. Purge Cassette, 5 Pack; Product Code: 0043-0003. 2. Impella RP US Pump Set; Product Code: 004334. 3. Purge Cassette, Packaged; Product Code: 0043-0002. Also included inside Product Code 0043-0003 above. Product Code 0043-0002 also includes innerm	ABIOMED Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
2.4 VOLT TAP LOCKING SCREW TAP TO 90MM	Synthes GmbH.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
8 mm SureForm 30 Gray	Intuitive Surgical Inc	https://www.bfarm.de/SharedDocs/K
Brand Name: Finesse BTK Multicath Product Name: Injectable Angioplasty Balloon Catheter	SUMMA THERAPEUTICS, LLC	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
Kits contain recalled Olympus biopsy valves	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
Medline ENFit G-tube Connector Medline kits	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
Medline neuro sponges	Medline Industries Inc.....	https://ade.sfda.gov.sa/Fsca/PublishD
Puracol and Puracol Plus Collagen Wound Dressings	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
Resuscitation Set with APL Valve (Mapleson Systems)	Armstrong Medical Ltd..	https://www.bfarm.de/SharedDocs/K
SECUDRAPE SURGICAL GOWNS	Sengewald Klinikprodukte GmbH	https://www.bfarm.de/SharedDocs/K
Sterile Radiology Procedure Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=218616
Swan Ganz	Edwards Lifesciences LLC	https://ade.sfda.gov.sa/Fsca/PublishD



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

