



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 80 dated 16/08/2026.

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. **80** / 2026

03-03-1448 H

16-08-2026

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 88

Medical Device	Manufacturer	Link
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Active Implantable Devices

Intera Oncology INTERA 3000 Hepatic Artery Infusion Pump, AP-0300H	Boston Scientific Corp	https://www.accessdata.fda.gov/scrip
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Anaesthetic and respiratory devices

Hillrom VOLARA System	Hill Rom Inc	https://www.accessdata.fda.gov/scrip
EVE family and Oxylog 600	Fritz Stephan GmbH.	https://www.bfarm.de/SharedDocs/K
Medin-NC3	medin Medical Innovations GmbH	https://www.bfarm.de/SharedDocs/K

Assistive products for persons with disability

E-motion M25 Wheels	Alber GmbH	https://www.bfarm.de/SharedDocs/K
Winn'Motion 150 & 175 patient lift.	WINNCARE Spain	https://www.bfarm.de/SharedDocs/K
Quantum 4Front 2Q6 E.g. 3 Stretto	Pride Mobility Products Corp	https://www.bfarm.de/SharedDocs/K
TD Navio Midi TD Navio Maxi	Tobii Dynavox LLC	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
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Diagnostic and therapeutic radiation devices

MR systems with SW versions R11.1 and R12.1	Philips Healthcare	https://www.bfarm.de/SharedDocs/K
Philips Azurion and Allura Systems	Philips Healthcare	https://apps.tga.gov.au/Prod/DRAC/a
BOSS Xe family	Wilcox Industries Corp.	https://www.accessdata.fda.gov/scip
Philips Incisive CT System	Philips Healthcare	https://apps.tga.gov.au/Prod/DRAC/a
SnapshotGLO Wound Imaging Device	KENT IMAGING, INC.	https://www.accessdata.fda.gov/scip

Electro mechanical medical devices

Omnipod DASH® Insulin Management System	Insulet Corporation.	https://www.accessdata.fda.gov/scip
Philips Avalon Fetal Monitor	Philips Healthcare	https://apps.tga.gov.au/PROD/DRAC/
ROSA ONE Brain Application	Zimmer Biomet	https://apps.tga.gov.au/Prod/DRAC/a
Affera HexaGEN RF Generators and HexaPulse PF Generators	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a



Medical Device	Manufacturer	Link
Affera Prism-2 Integrated Mapping System	Medtronic Inc.	https://apps.tga.gov.au/Prod/DRAC/a
Rapid Refill™ Continuous Injection System	Boston Scientific Corp	https://www.bfarm.de/SharedDocs/K
Solar GI System (Water Perfusion)	Laborie Medical Technologies, Corp	https://www.accessdata.fda.gov/scrip
Emano Flow	Emano Metrics, Inc	https://www.accessdata.fda.gov/scrip
ENROUTE Transcarotid Neuroprotection System Plus (NPS Plus)	Boston Scientific Corp	https://apps.tga.gov.au/Prod/DRAC/a/rn-detail.aspx?k=RC-2026-RN-00533-1
FARASTAR Ablation Generator EU, Pulsed Field Ablation Generator, PFA catheter	Boston Scientific Corp	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221149
Infusomat Space P	B. BRAUN MEDICAL INC	https://www.bfarm.de/SharedDocs/K
Olympus 4K UHD LCD Monitor	Olympus Corporation of the Americas	https://www.accessdata.fda.gov/scrip
Power F2 Powered Fastening System	Ferno-Washington Inc	https://www.accessdata.fda.gov/scrip

Hospital Hardware

HKH 8820 Wall Holder	MAQUET Cardiopulmonary GmbH	https://www.bfarm.de/SharedDocs/K
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Medical Device

Manufacturer

Link

In vitro diagnostic devices

GC Agar Base (150mm) 10/PK R04030, GC Agar Base (100mm) 10/PK R01460	Remel Inc	https://www.accessdata.fda.gov/scr
Oncomine DX Express Test Panel	Thermo Fisher Scientific Oy	https://www.bfarm.de/SharedDocs/K
The RIDAPlex Respiratory Pathogens C 16 well Step 1	AusDiagnostics Pty Ltd	https://apps.tga.gov.au/Prod/DRA C/a
ENTEROVIRUS R-GENE	bioMerieux Inc	https://apps.tga.gov.au/Prod/DRAC/a
Anti-Spermatozoa Antibody (ASA) serum ELISA	Demeditec Diagnostics GmbH.	https://www.bfarm.de/SharedDocs/K
Sperm Antibody ELISA	DRG Instruments GmbH.	https://www.bfarm.de/SharedDocs/K
Sperm Antibody ELISA	DRG Instruments GmbH	https://www.bfarm.de/SharedDocs/K
ST AIA-Pack Testosterone	Tosoh Bioscience In.	https://www.accessdata.fda.gov/scr

Medical Software

Atrio v5.0.1 and Atrio Plus v1.1.0 - 2.0.0	Alerte Digital Health Pte Ltd	https://apps.tga.gov.au/Prod/DRAC/a
RayCare 2024A SP1 RayCare 2024A SP4	RaySearch Laboratories AB (publ)	https://www.accessdata.fda.gov/scr
MiniMed" 780G Insulin Pump, software version 6.62 OUS	Medtronic MiniMed	https://www.accessdata.fda.gov/scr
MiniMed GoTM app	Medtronic MiniMed	https://www.bfarm.de/SharedDocs/K
Raystation 2024A, 2024B, v2025	RaySearch Laboratories AB (publ)	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
The Mako 4 system running the Total Hip Arthroplasty (THA) 4.2 and THA 5.0 applications	MAKO Surgical Corp	https://apps.tga.gov.au/Prod/DRAC/a
TheraSphere 360 Y-90 Management Platform	Boston Scientific Corp	https://www.accessdata.fda.gov/scr

Non-active implantable devices

Depuy Synthes, ATTUNE Revision Hinge Knee Hinge Insert Components	DePuy International Limited	https://www.accessdata.fda.gov/scr
Mariner Polyaxial Head components used within the Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation	https://apps.tga.gov.au/Prod/DRA/C/arn-detail.aspx?k=RC-2026-RN-00477-1
Phantom Hindfoot TCC/TC Ball Tipped Guide Rod 3.0 x 800mm Sterile	Paragon 28, Inc	https://apps.tga.gov.au/Prod/DRAC/a
Short Monobloc Stem Broaches	Medacta International SA	https://www.accessdata.fda.gov/scr
EMPOWR 3D KNEE INS, 11L 14MM	Encore Medical, L.P	https://www.accessdata.fda.gov/scr
Figulla Flex II ASD Occluder and its Procedure Pack	Occlutech International AB	https://www.bfarm.de/SharedDocs/K
Sterile Tourniquet Hoses	Zimmer Biomet	https://www.accessdata.fda.gov/scr
Bone Level Tapered Implant, Ø 4.1mm RC, SLActive® 12mm, Roxolid®, Loxim	Straumann USA, LLC	https://www.bfarm.de/SharedDocs/K
Pipeline Flex Embolization Device with Shield Technology, 3.00 mm x 20 mm 027	Micro Therapeutics Inc (DBA ev3 Neurovascular)	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2213



Medical Device	Manufacturer	Link
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SeaSpine Polyaxial Head	SeaSpine Orthopedics Corporation	https://www.accessdata.fda.gov/scrip
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Single-use devices

10ml Syringe LuerLok Tip	Mentor Texas LP	https://www.accessdata.fda.gov/scrip
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A M S, ALIGNED MEDICAL SOLUTIONS surgical convenience kit	Windstone Medical Packaging, Inc	https://www.accessdata.fda.gov/scrip
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BLEPHADEMODEX	Laboratories THEA S.A.S	https://www.bfarm.de/SharedDocs/K
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Climber Guiding Catheter 6F 3.5EBU shape	PendraCare International B.V	https://www.bfarm.de/SharedDocs/K
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ConvaVAC™ NPWT Dressings	ConvaTec	https://www.bfarm.de/SharedDocs/K
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Convenience kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
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Convenience Kits	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
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Custom Tubing Packs (CTPs)	MAQUET Cardiopulmonary GmbH	https://www.bfarm.de/SharedDocs/K
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ENFit ExSet Strl 60 2.0ml PV 1ct EN	Medela INC	https://www.accessdata.fda.gov/scrip
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EOPA 3D Arterial Cannulae and EOPA Elongated One-Piece Arterial Cannulae	Medtronic Inc	https://apps.tga.gov.au/PROD/DRAC/
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Impella Set with smart assist Introducer Kit for Impella CP	ABIOMED Inc	https://www.accessdata.fda.gov/scrip
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Medline Convenience kits containing recalled Swan-Ganz Catheters.	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
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Medical Device	Manufacturer	Link
Med-Stop Vacuum Controller	Medline Industries Inc	https://www.bfarm.de/SharedDocs/K
NephroMax High Pressure Nephrostomy Balloon Catheters	Boston Scientific Corp	https://apps.tga.gov.au/PROD/DRAC/
OPN NC	SIS Medical AG	https://www.bfarm.de/SharedDocs/K
Pilling Wecksorb Neurosponges	Teleflex Medical	https://www.accessdata.fda.gov/scr
Radial Jaw 4 Biopsy Forceps	Boston Scientific Corp	https://www.bfarm.de/SharedDocs/K
TS Barefiber 600um,3m,singleuse,sterile	KLS Martin GmbH + Co. KG	https://www.bfarm.de/SharedDocs/K
Various procedure packs containing BD Connecta Stopcocks	Medline Industries Inc	https://apps.tga.gov.au/Prod/DRAC/a
Covidien Shiley Disposable Decannulation Plug	Covidien LLC	https://www.accessdata.fda.gov/scr
5008X Blood Tubing Set, 24 units per case	Fresenius Medical Care.	https://www.accessdata.fda.gov/scr
Aquacel Ag Surgical SP	ConvaTec	https://www.accessdata.fda.gov/scr
BAL Flush Syringe SS, 10 mL	Jiaying Tianhe Pharmaceutical.,Co.,Ltd	https://www.bfarm.de/SharedDocs/K
BD® neXus Disposable Infusion Sets.	BD Switzerland Sarl	https://www.bfarm.de/SharedDocs/K
HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4-PRONG LUERS	Baxter Healthcare	https://www.bfarm.de/SharedDocs/K
IV Non-Dedicated Gravity Admin sets.	ICU Medical, Inc	https://www.bfarm.de/SharedDocs/K
LARYNGEAL MASK, PVC, disposable	ZARYS International Group	https://www.bfarm.de/SharedDocs/K



Medical Device	Manufacturer	Link
MEDLINE 111 GRAVITY SET W/3 Needle Free Y-Sites	BD Switzerland Sar	https://www.accessdata.fda.gov/scr
Medline Convenience Kits, OPEN HEART PEDS PACK, ANESTHESIA KIT PEDS	Medline Industries Inc	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=221031
Power Trialysis ShortTerm Catheter, DuoGlide ShortTerm Dialysis Catheter, Soft Tissue Biopsy Tray	Bard Access Systems.	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=220791
Reprocessed Electrophysiology Catheters and Ultrasound Catheters	Medline Industries Inc	https://www.accessdata.fda.gov/scr
Sontek Swivel Y Airway Connector	Teleflex Medical	https://apps.tga.gov.au/Prod/DRAC/a
THERAKOS® CELLEX® Photopheresis Procedural Kit	Mallinckrodt Pharmaceuticals Ireland Limited	https://www.bfarm.de/SharedDocs/K
V-Loc 90 and 180 Suture Products	Medtronic Inc	https://apps.tga.gov.au/Prod/DRAC/a
V-Loc 90 and 180 Suture Products	Medtronic Inc	https://www.bfarm.de/SharedDocs/K



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.

Shanifa

**Ph. Ibrahim Nasser Al Rashdi
Director General**

