

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 100 dated 18/10/2026.

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. 100 / 2026

07-05-1448 H

18 -10-2026

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 33

Medical Device	Manufacturer	Link
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Active Implantable Devices

Inspire® Therapy	Inspire Medical Systems Inc.	https://www.bfarm.de/SharedDocs/K
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Anaesthetic and respiratory devices

HAMILTON-C6 Ventilator	HAMILTON MEDICAL AG	https://apps.tga.gov.au/Prod/DRAC/a
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Assistive products for persons with disability

Lets Get Up, Lets Get Up L	Trust Care AB	https://www.bfarm.de/SharedDocs/K
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Rollator, Bariatric, Basic Steel,	Medline Industries Inc	https://www.accessdata.fda.gov/scrip
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Complementary therapy devices

Medline Basic Homecare Beds and Medlite Homecare Beds and Accessories	Medline Industries Inc	https://www.accessdata.fda.gov/scrpts/cdrh/cfdocs/cfres/res.cfm?id=2225
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Diagnostic and therapeutic radiation devices

Alphenix INFX-8000C/B5	Canon Inc	https://www.accessdata.fda.gov/scrip
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VERSA Accessory Cart	Ziehm Imaging GmbH.	https://apps.tga.gov.au/Prod/DRAC/a
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Medical Device	Manufacturer	Link
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Electro mechanical medical devices

Glypto Device, Glypto Cryo Machine	Limitless Cryo Spa LLC	https://www.accessdata.fda.gov/scr
HOPKINS Telescope 30, 4mm	KARL STORZ SE & Co. KG.	https://www.accessdata.fda.gov/scr
Intellijoint Navigation System	Intellijoint Surgical, Inc	https://www.accessdata.fda.gov/scr
MiniMed Flex	Medtronic MiniMed...	https://www.accessdata.fda.gov/scr
NovaSeq 6000Dx including DRAGEN Server	Illumina Inc	https://www.accessdata.fda.gov/scr

Hospital hardware

CNS-6200 Series Central Nurse Station	Nihon Kohden Corporation..	https://www.accessdata.fda.gov/scr
HexaVue Focus	STERIS Corporation..	https://www.accessdata.fda.gov/scr
SEDIPLAST	Polymedco, Inc	https://www.accessdata.fda.gov/scr
Washer Disinfectors	Kluge & Fielitz GmbH	https://www.bfarm.de/SharedDocs/K

In vitro diagnostic devices

DxC 500 AU Clinical Chemistry Analyzer	Beckman Coulter....	https://www.accessdata.fda.gov/scr
DxC 500i Clinical Analyzer	Beckman Coulter....	https://www.accessdata.fda.gov/scr

Medical software

IntelePACS	Intelerad Medical Systems Inc..	https://apps.tga.gov.au/Prod/DRAC/a
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Non-active implantable devices

CHARLOTTE CLAW	Wright Medical Technology, Inc.	https://www.accessdata.fda.gov/scr
My3D Personalized Pelvic Implant	Onkos	https://www.accessdata.fda.gov/scr

Medical Device	Manufacturer	Link
Reusable devices		
Sharp Uterine Curettes / Gynaecological Curettes	INKA Surgical Instruments	https://apps.tga.gov.au/Prod/DRAC/a
Single-use devices		
BARD EP XT DECAPOLAR STEERABLE, DIAGNOSTIC EP CATHETER	Stryker Communications.....	https://www.accessdata.fda.gov/scr
Battle Bandage	Safeguard US Operating LLC	https://www.accessdata.fda.gov/scr
DORMO-STRIP Single Use Vein Stripper	TELIC, S.A.U.	https://www.bfarm.de/SharedDocs/K
Expressaire TOURNIQUET	Global, LLC. dba Anatomy Supply Partners, L	https://www.accessdata.fda.gov/scr
Ferndale Laboratories, Mastisol Skin Adhesive	Custom Interventional Pain Management, LLC	https://www.accessdata.fda.gov/scr
HALYARD Laparoscopy Comprehensive Pack II	GRI Medical & Electronic Technology Co., Ltd.	https://www.accessdata.fda.gov/scr
Halyard Trays and Kits containing Lubricant	Avid Medical, Inc.	https://www.accessdata.fda.gov/scr
Presource Packs containing Medtronic Microstream Components: Intubation Kit	Cardinal Health 200, LLC..	https://www.accessdata.fda.gov/scr ts/cdrh/cfdocs/cfres/res.cfm?id=2225
TufTex Over-the-Wire Embolectomy Catheter	LeMaitre Vascular, Inc.	https://www.accessdata.fda.gov/scr
Various Procedure Packs containing BAG DRAWSTRING DUAL CORD 46X50CM	Medline Assembly Australia Pty Ltd	https://apps.tga.gov.au/Prod/DRAC/a rn-detail.aspx?k=RC-2026-RN-00748-
VERIFY Biological Products	STERIS Corporation..	https://www.accessdata.fda.gov/scr

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

