## Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

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 <u>5</u> dated <u>9///2023</u> Regarding NCMDR Recall of Philips 12-Lead Chest Lead-set from (mfr: Philips Healthcare).

## Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





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Circular No. **5** / 2023

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09 -01-2023



## Recall of Philips 12-Lead Chest Lead-set from Philips Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=18402">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=18402</a>
Product	Philips 12-Lead Chest Lead-set.
Description	Cable/lead, electrocardiograph.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science & Industry.
The affected products	Product code: 989803151691 & 989803151671.
Reason	An issue related to the orientation of the internal wiring of the above Philips 12-Lead Chest Lead-set.
Action	<ol> <li>Discard the impacted lead sets according to local disposal requirements.</li> <li>Customers will be contacted by Philips to provide instruction on how to order replacement lead-set. However, customers are advised that until the replacement stock become available, they can use the existing stock at their discretion.</li> <li>Contact the local agent for remedial action.</li> </ol>
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: <a href="Med-device@moh.gov.om">Med-device@moh.gov.om</a>

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Dr. Mohammed Hamdan Al-Rubaie

Director General





