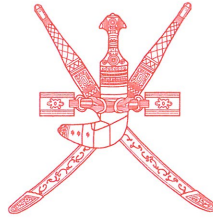


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عمان  
وزارة الصحة  
الديرة العامة للأدوية  
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. 74..... dated 26/3/23 Regarding Recall of HeartStart MRx Monitor/Defibrillators from 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

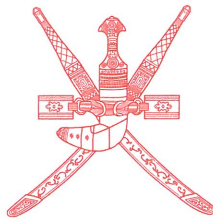
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مسقط

Circular No. 74 / 2020

-03-1441 H

Ref: 54/2020

-03-2020

## Recall of HeartStart MRx Monitor/Defibrillators from Philips Healthcare

Source of Recall	<a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15113">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=15113</a>																												
Product	HeartStart MRx Monitor/Defibrillators																												
Manufacturer	Philips Healthcare																												
Local Agent	Mustafa Sultan																												
The affected products	<table border="1"><thead><tr><th colspan="4">Commercial (Sales) Product Numbers</th></tr></thead><tbody><tr><td>M3535A</td><td>861288</td><td>M3536M4</td><td>861483</td></tr><tr><td>M3536A</td><td>861289</td><td>M3536M5</td><td>861484</td></tr><tr><td>M3536M</td><td>861464</td><td>M3536M6</td><td>861491</td></tr><tr><td>M3536MC</td><td>861465</td><td>M3536M7</td><td>860396</td></tr><tr><td>M3536M2</td><td>861481</td><td>M3536M8</td><td>860397</td></tr><tr><td>M3536M3</td><td>861482</td><td>M3536M9</td><td>860398</td></tr></tbody></table>	Commercial (Sales) Product Numbers				M3535A	861288	M3536M4	861483	M3536A	861289	M3536M5	861484	M3536M	861464	M3536M6	861491	M3536MC	861465	M3536M7	860396	M3536M2	861481	M3536M8	860397	M3536M3	861482	M3536M9	860398
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Reason for Recall	Philips has received a number of reports of HeartStart MRx Monitor/Defibrillators that have suffered internal damage and were not able to deliver therapy after having been dropped or subjected to a severe mechanical shock, even though the device did not have visible external damage or the Ready for Use ("RFU") indicator on the unit did not immediately indicate a problem.																												
Action	1. FOR further instruction and necessary action Kindly check your local agent																												
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 Director of Medical Device Control contact E-mail <a href="mailto:dg-padc@moh.gov.om">dg-padc@moh.gov.om</a>																												

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

