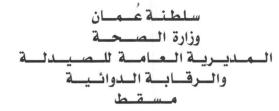
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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,

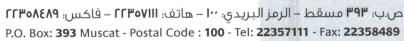
Please find attached our Circular No........ dated 22.15.1.22. Regarding GHC recall of Medfusion 3500 and 4000 Syringe Pumps from (mrf: Smiths Medical ASD, Inc).

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







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



وزارة الصح المدرية العامية لل والرقابة الدوائ

Circular No. 97/2022

23-10-1443 H

22 -05-2022

Recall of Medfusion 3500 and 4000 Syringe Pumps from Smiths Medical ASD, Inc.

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Source	GHC- Gulf Health Council.
Product	Medfusion 3500 and 4000 Syringe Pumps.
Manufacturer	Smiths Medical ASD, Inc.
The Affected Products	All Medfusion 3500 pumps and all versions of the Medfusion 4000 pump.
Local Agent	Muscat Pharmacy & Stores LLC.
Reason	Due to a software issues that can potentially impact infusion delivery. Over- or under-delivery can occur if the following specific sequence of events occur: a bolus or loading dose is interrupted, the pump is primed, and the infusion is restarted. Use of the affected syringe pumps may cause serious adverse health consequences including death.
Action	 Locate all Medfusion® 3500 and 4000 Syringe Pumps in possession and verify the firmware version to determine if the pump(s) is impacted by this notice. Contact the local agent for remedial action.
Product Picture	Figure 1 - Medfusion 3500 and 4000 Syringe Pumps
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL





