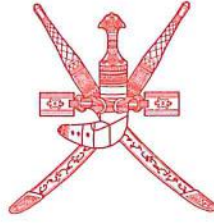


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَا مَجَلَا
وَزَارَةَ الصِّحَّةِ
المديرية العامة للصحة
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. 82/2020 dated 6/4/2020 Regarding Safety Alerts of T34 TM and T34LTM (T60TM) Ambulatory Syringe Pumps from CME (a BD Company)

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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سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلانية
والرقابة الدوائية
مسقط


Circular No. 82/2020

12 -07-1441 H

Ref: 47/2020

06 -04-2020

Safety Alerts of T34 TM and T34LTM (T60TM) Ambulatory Syringe Pumps from CME (a BD Company)

Source of Recall	Gulf Health Council
Product	T34 TM and T34LTM (T60TM) Ambulatory Syringe Pumps
Manufacturer	CME (a BD Company)
Local Agent	Mustafa Sultan Science & Industry
The affected products	ALL Serial Numbers
Reason for Recall	Through post-marketing surveillance reports regarding the above pump It turns out that the mechanism of the syringe pump motor block may be affected over time, this may reduce the pumping rate Without sounding an alarm from the pump.
Action	<ol style="list-style-type: none">1. Kindly check your stock, contact your local agent for remedial action2. User required to inspect the pump before each use3. If you see white plastic debris on the lead screw, immediately stop using the pump and send it to BD or your chosen service provider for repair4. A reminder that it's vital to regularly check that an infusion is running as expected.5. Technical staff should be aware of updated service manual advice for pump maintenance. Contact BD to obtain it if required
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 Med-device@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

