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 244 dated 26/11/2023 Regarding NCMDR Recall of Tracheostomy Care and Cleaning Trays from (mfr: Medline Industries 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







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سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

MovingForward with Confidence

Circular No. 244 / 2023

12 -05-1445 H

26 -11-2023

Recall of Tracheostomy Care and Cleaning Trays from Medline Industries Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19770
Product	Tracheostomy Care and Cleaning Trays.
Description	Placed into a surgical opening of the trachea.
Manufacturer	Medline Industries Inc.
Local agent	Golden Target
The affected products	Item Codes: DYND40580 Lot Numbers: 6052203006, 6052203022, 6052204005, 6052204010, 6052205024, 6052206003, 6052206010, 6052206011, 6052206020, 6052206021, 6052207009, 6052207013, 6052207014, 6052207015, 6052208021, 6052208022, 6052209009, 6052209025, 6052209026, 6052212023, 6052301031, 6052303011, 6052303013, 6052303014, 6052304020, 6052305007, 6052305019, 6052305026, 6052306004, 6052306014, 6052306015, 6052306026, 6052306032, 6052307006, 6052307011, 6052307012
Reason	The tracheostomy brush (a component within the Tracheostomy Care and Cleaning Kits) having a sharp edge at the tip that can potentially puncture tubing during use and/or cause user injury.
Action	 Please immediately quarantine all affected lots. Contact the local agent for remedial action.
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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



