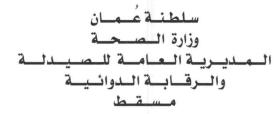
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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...7.5...... dated 20/4/2022 Regarding NCMDR Recall of Teneo Treatment Centers from (mrf: Dentsply Sirona, 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



سلطنة عُـمان وزارة الـصحـة الـمـديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مسقط

Circular No. 75 / 2022

8-09-1443 H

20-04-2022

Recall of Teneo Treatment Centers from Dentsply Sirona, Inc

	Treatment Centers from Dentspiy Strong, Inc
Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=16108
Product	Teneo Treatment Centers.
Description	Dental products - dental treatment units.
Manufacturer	Dentsply Sirona, In.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Production 2009-2012 Type REF. 6202860 and REF. 6364157
Reason	A potential assembly problem, which in very rare cases, can lead to the loosening of a component (bearing pin) and in even rarer cases the component, which is needed to position the seat carrier of the Teneo treatment center can move out of its bearing and the seat might move into a lying position.
Action	 The replacement of affected component will be done if needed. The replacement inspection are completely free of charge for you. Contact the local agent for remedial action.
Product Picture	S. Contact the local agent for femoural 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al-Rubaie
DIRECTOR GENERAL





ص.ب: ۳۹۳ مسقط الرماز البرائيدي – ماتف: ۲۲۳۰ مسقط الرماز البرائيدي – ماتف: ۳۹۳ مسقط ۲۲۳۰ مسقط ۳۹۳ ... P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489