

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سِلاطِنَا اُمَانَا  
وَزَارَةِ الصِّحَّةِ  
الْمَدِيرِيَّةُ الْعَامَّةُ لِلصِّدْقِ  
وَالرَّقَابَةِ الدَّوَلِيَّةِ  
مَسْقَطَا

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...184... dated 07/10/2020 Regarding NCMDR Field Safety Notice of Evis Exera II from (mfr: Olympus).

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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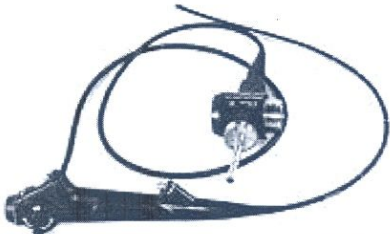
سلطنة عمان  
وزارة الصحة  
المديرية العامة للأدوية  
والرقابة الدوائية  
مسقط

Circular No. 184/2020

19 -02-1442 H

07 -10-2020

## FSN of Evis Exera II from Olympus.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=15362">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=15362</a>
Product	Evis Exera II.
Description	Video Bronchoscopes
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product (Model No.): 1- EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180 (BF-1T180), 2- EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160 (BF-XT160) Serial number All.
Reason	Due to the large channel diameter, these devices are associated with a potential risk of patient infection due to inadvertent retention of biomaterial when manual cleaning and brushing are not performed as instructed.
Action	1. Carefully read and follow the Reprocessing Manual of the affected devices. 2. Contact the local agent for remedial action.
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 Department of Medical Device Control through an E-mail: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>



Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL