



Circular No. 28 / 2023

نتقدم بـ  
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07-07-1444 H

30-01-2023

**Recall of Ultrasound Gel Soft from Saudi Mais for Medical Products.**

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18419">https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&amp;rid=18419</a>
Product	Ultrasound Gel Soft.
Description	Ultrasound.
Manufacturer	Saudi Mais for Medical Products.
The affected products	US-GEL, all lots.
Local agent	Taiba Medserv.
Reason	Detection of Bacteria in product named as "Burkholderia cepacian Complex". for all lots available 2022.
Action	1. Quarantine affected products immediately. 2. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General





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 28 dated 30/1/2023 Regarding NCMDR Recall of Ultrasound Gel Soft from (mfr: Saudi Mais for Medical Products).

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







Kingdom of Saudi Arabia  
Saudi Food & Drug Authority

Medical Devices Sector

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# NCMDR

National Center for Medical Devices Reporting


المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

## NCMDR Recall

**Reference Number:** mdprc 011 01 23 000

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**Date submitted:** 1/19/2023

<b>Manufacturer:</b>	Saudi Mais for Medical Products
<b>Device Type:</b>	Ultrasound Gel Soft
<b>Description:</b>	Ultrasound
<b>Medical Device Identifier:</b>	US-GEL, all lots
<b>Reason of Field Safety Corrective Action:</b>	Detection of Bacteria in product named as "Burkholderia cepacian Complex". for all lots available 2022.
<b>Remedy Action:</b>	Quarantine affected products immediately. Customer services will collect the affected products.
<b>Athorized Representative/Importer/Distributor:</b>	Saudi Mais Co. For Medical Products
<b>Report Source:</b>	NCMDR
<b>Source Ref. Number:</b>	DE2993CC422A8
<b>SFDA Comments:</b>	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
<b>Attachments:</b>	 Saudi Mais Co. for Medical Products.pdf

[View History](#)

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