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

سلطنة عمان
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.** 209 **dated** 8/11/2022 **Regarding NCMDR Field Safety Corrective Action of Sofia SARS Antigen FIA Package Insert from (mfr: Quidel Corporation).**

**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**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

**Sultanate of Oman**
**Ministry of Health**
**Directorate General of Pharmaceutical Affairs and Drug Control**
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سلطنة عمان
وزارة الصحة
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مسقط

# Circular No. 209 / 2020

22 -03-1442 H

08 -11-2020

**Field Safety Corrective Action of Sofia SARS Antigen FIA Package Insert from Quidel Corporation.**

| | |
|---|---|
| Source | NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=15415 |
| Product | Sofia SARS Antigen FIA Package Insert. |
| Description | Coronavirus antigen detection test system. |
| Manufacturer | Quidel Corporation. |
| Local agent | Health for All. |
| The affected products | 1438900EN00 (03/20) and 1438901EN00 (05/20). |
| Reason | Use of the specific viral transport medium products may result in False-positive results. Directly testing from specimens (NS or NP swab) is recommended. |
| Action | 1. Discontinue the use of affected package inserts.<br>2. Access the updated instructions for use labeling which can be located by going to quidel.com/docs and selecting the Sofia SARS Antigen FIA Package Insert document.<br>3. In the event that your facility has used Remel viral transport media products (e.g., M4, M4RT, M6), please contact Quidel Technical Support to discuss your results.<br>4. Contact 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: Med-device@moh.gov.om |

**Dr. Mohammed Hamdan Al Rubaie**

**Director General**

SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - ص . ب: ٣٩٣ مسقط - الرمز البريدي
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
**Medical Devices Sector**
قطاع الأجهزة الطبية

**NCMDR**
**National Center for Medical Devices Reporting**
المركز الوطني لبلاغات الأجهزة والمنتجات الطبية



## U.S FDA Recall

**Reference Number:** mdprc 036 10 20 000 **Back**
**Date submitted:** 10/29/2020

| | |
|---|---|
| **Manufacturer:** | Quidel Corporation |
| **Device Type:** | Sofia SARS Antigen FIA Package Insert |
| **Description:** | Coronavirus antigen detection test system. |
| **Medical Device Identifier:** | 1438900EN00 (03/20) and 1438901EN00 (05/20) |
| **Reason of Field Safety Corrective Action:** | Use of the specific viral transport medium products may result in False-positive results. Directly testing from specimens (NS or NP swab) is recommended. |
| **Remedy Action:** | Customers were asked to take the following actions:<br>1) Discontinue the use of affected package inserts.<br>2) Access the updated instructions for use labeling which can be located by going to quidel.com/docs and selecting the Sofia SARS Antigen FIA Package Insert document.<br>3) In the event that your facility has used Remel viral transport media products (e.g., M4, M4RT, M6), please contact Quidel Technical Support to discuss your results. |
| **Athorized Representative/Importer/Distributor:** | ABDULLA FOUAD HOLDING COMPANY |
| **Report Source:** | https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=183267 |
| **Source Ref. Number:** | Z-0124-2021 |
| **SFDA Comments:** | SFDA urges all hospitals that have devices subjected to this FSCA to contact the company. |
| **Attachments:** | No Attachments |

**View History**