Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
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 167 **dated** 28/11/24 **Regarding SFDA Field Safety Corrective Action of LIAISON Q.S.E.T. Device Plus from (mfr: DiaSorin Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center
ISO

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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سلطنة عُمان
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Circular No. 167 **/ 2024**

Moving Forward with Confidence | رؤية عُمان 2040

26 -05-1446 H
28 -11-2024

Field Safety Corrective Action of LIAISON Q.S.E.T. Device Plus from DiaSorin Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/182
Product	LIAISON Q.S.E.T. Device Plus.
Manufacturer	DiaSorin Inc.
Local agent	Al Zahrawi Medical Supplies.
The affected products	Unique Device Identifier(s) (UDI-DI): 80567713190605F Device Model/Catalogue/part number(s): 319060 Affected serial or lot number range: 225084, 233154, 223244, 230094, 259144, 224244, 219104, 228174, 251234, 232094, 236174, 252244, 224124, 210204, 223274, 217134 , 221214, 221294, 234114, 228224, 232294, 205144, 229224, 222314.
Reason	Internal investigation by the manufacturer has determined that 0.14% of the tubes in the lots identified may have loose clear caps. The loose clear caps may allow leakage of the buffer from the tube.
Action	1. Devices should be inspected for loose clear caps prior to use. The user should confirm that the clear cap is tight by grasping the cap and twisting. 2. If the cap is loose, the device should be discarded. Do not attempt to use the device as the loose clear cap may have allowed the buffer to leak and the buffer volume may be insufficient. 3. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center | ISO

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: **393** Muscat - Postal Code: **100** - Tel: **22357111** - Fax: **22358489**
@DSCPHO Email: **dscpho@moh.gov.om**