

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيد
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)
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. 234 dated 09/12/2020 Regarding NCMDR Field Safety Notice of Omixon HLA Twin CE 4.2.0 from (mfr: Omixon Biocomputing Ltd).

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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Circular No. 234/2020

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09 -12-2020

Field Safety Notice of Omixon HLA Twin CE 4.2.0 from Omixon Biocomputing Ltd.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=15439
Product	Omixon HLA Twin CE 4.2.0.
Description	In-vitro diagnostics - instruments, apparatuses and systems.
Manufacturer	Omixon Biocomputing Ltd.
The affected products	Omixon HLA Twin CE 4.2.0.
Reason	Markups* are missing on exported results in case of PDF; JSON; HPRIM and HML types of export.
Action	1. It is strongly recommended to crosscheck the exported results versus the displayed result in the software while using Omixon HLA Twin CE 4.2.0. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

