

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطَنَة عُومَان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

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..235... dated 29/12/2018 Regarding NCMDR Field Safety Notice of Masterclave 10 and Masterclave 20 from (mfr: BioMerieux Inc).

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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وزارة الصحة
المديرية العامة للأدوية
والسراويل الدوائية
مسقط

Circular No. 235/2020

23 -04-1442 H

09 -12-2020

Field Safety Notice of Masterclave 10 and Masterclave 20 from BioMerieux Inc.

Source	NCMDR - National Centre Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15454
Product	Masterclave 10 and Masterclave 20.
Description	In vitro diagnostic devices
Manufacturer	BioMerieux Inc.
Local agent	Al Hashar Pharmacy.
The affected products	Masterclave 10 ref 417118 and Masterclave 20 ref 417130 software version: cannelloni 1.0.7503
Reason	A software anomaly associated with version Cannelloni 1.0.7503.
Action	1. A new software version (version cannelloni 1.0.7601) has been made available that corrects this anomaly. 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: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie

Director General