

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..18...6... dated 27/10/2021. Regarding GHC Recall of Recirculator 8.0 Disposable Lavage Kits from (mrf: Eight Medical International).

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





Circular No. 186/2021

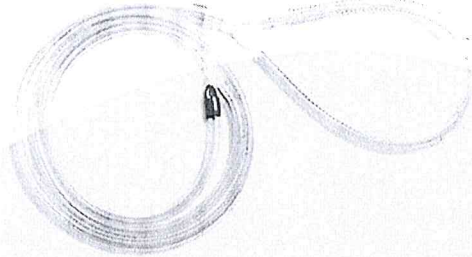
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27 -10-2021

تتقدم بثقة
Moving Forward
with Confidence



Recall of Recirculator 8.0 Disposable Lavage Kits from Eight Medical International.

Source	GHC- Gulf Health Council.
Product	Recirculator 8.0 Disposable Lavage Kits.
Manufacturer	Eight Medical International.
The affected products	Product Code: 8100 . Lot Numbers: 20021361, 20202106, 20202106, 20018480, 19854186, 20019438, 20018480, 19854186, 19854185, 20202106, 20019438, 19854184, 20202106, 20018480, 20202106, 20018480, 18687686
Reason	Eight Medical is recalling the Recirculator 8.0 Disposable Lavage Kit because the disposable heating element within the kit may release aluminum into the fluid during warming therapy. When the fluid circulates through the patient's body, the patient can be exposed to high levels of aluminum, which can be toxic and cause serious adverse events including death.
Action	1. Do not use any affected lots, and contact the company to arrange for a replacement. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL