



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 87 dated 30/4/2023 Regarding NCMDR FSCA of ACL Elite/Elite Pro Hemostasis Testing Systems from (mfr: Instrumentation Laboratory SpA, a Werfen Company).

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. 87/2023

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Oman Vision

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30 -04-2023

FSCA of ACL Elite/Elite Pro Hemostasis Testing Systems from Instrumentation Laboratory SpA, a Werfen Company.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=19509
Product	ACL Elite/Elite Pro Hemostasis Testing Systems
Description	In-vitro diagnostics - haematological, histological and cytological products.
Manufacturer	Instrumentation Laboratory SpA, a Werfen Company.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	ACL Elite 0000880311, ACL Elite Pro 0001000311, ACL Elite Refurb 0000880311R, ACL Elite Pro Refurb 0001000311R.
Reason	A Mandatory Test Library upgrade on the ACL Elite/Elite Pro Hemostasis Testing System (Test Library 02.05.00).
Action	1. The local Werfen distributor will install the 02.05.00 Mandatory Test Library. 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 through the E-mail: Med-device@moh.gov.om


Dr. Mohammed Hamdan Al Rubaie
Director General

