



نتقدم بثقة
Moving Forward
with Confidence



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 183 dated 27/8/23 Regarding NCMDR recall of Zvu® Functional GI Software from (mfr: Diversatek Healthcare.).

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





ننمض بثقة
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Circular No. 183/2023

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27 -08-2023

Recall of Zvu® Functional GI Software from Diversatek Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19663
Product	Zvu® Functional GI Software.
Description	Esophageal manometry studies Software.
Manufacturer	Diversatek Healthcare.
The affected products	Part Number ZVU-3 Version 3.3.2109.6 Shipped between 5/4/2023 and 7/6/2023.
Reason	The product label contains the incorrect software revision. It is labelled as revision 3.3.0 but it contains revision 3.2.0.
Action	1. Please identify those devices with above version number and discard them. 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

