



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 157 dated 04/11/2024 Regarding SFDA Recall of Level 1® DI-50 Normothermic I.V. Fluid Administration Sets from (mfr: Smiths Medical ASD, Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



Circular No. 157/2024

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02-05 1446 H
04-11-2024

Recall of Level 1® DI-50 Normothermic I.V. Fluid Administration Sets from Smiths Medical ASD, Inc.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/145
Product	Level 1® DI-50 Normothermic I.V. Fluid Administration Sets.
Manufacturer	Smiths Medical ASD, Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Affected SKU: DI-50 Lot Number: 4046857, 4052422, 4053958, 4057793, 4060925, 4068107, 4071912, 4080962, 4084073, 4101760, 4101761, 4101762, 4114258, 4136435, 4146576, 4136436, 4146577, 4158824, 4177203, 4201887, 4177204, 4231847, 4232865, 4232863, 4235857, 4252864, 4252865, 4312527, 4312530, 4315435, 4317048, 4317049, 4449214, 4461479, 4463771, 4469633
Reason	Smiths Medical has become aware of users not being able to fit some Level 1 DI-50 Normothermic I.V. Fluid Administration Sets properly into the interlock block of the Level 1 Fast Flow Fluid Warmer.
Action	1. Discontinue use and destroy all DI-50 administration sets following your institution's process for discarding. 2. If destruction is not immediately possible at your facility, then the product should be quarantined until disposal. 3. Smiths Medical can offer alternate products in place of the DI-50. 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: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan AlRubale
Director General

