

		ADVISORY NOTICE FORMAT		Standard Reference	MDR 2017
				Document No	F/MR/07
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ADVISORY NOTICE ISSUED BY	MEDIVISION HEALTH CARE
DATE OF ISSUE	27-06-2026

DEVICE DETAILS	
DEVICE NAME	INFUSION SET-NV
BATCH NO./SERIAL NO.	KT-071
MFG. DATE	11/2024
EXP. DATE	10/2027

It has been brought to the attention of the company **MEDIVISION HEALTH CARE** that the following defect

DESCRIPTION OF THE PROBLEM

Certain observations regarding the above-mentioned batch have been communicated by the regulatory authority. As a precautionary measure, the company has initiated a recall of the affected batch.

DETAILS OF THE ISSUE / COMPLAINT:

It has been brought to the attention of **MEDIVISION HEALTH CARE** through a notice received from the **Office of the Commissioner, Food & Drugs Control Administration, Dr. Jivraj Mehta Bhavan, Block No. 8, 1st Floor, Gujarat State, Gandhinagar - 382010**, that certain observations have been reported regarding the above-mentioned product. Accordingly, in compliance with the directions of the competent authority, the company has initiated a recall of the affected batch from the market.

Complaint Received Date	23-06 -2026
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RISK CLASSIFICATION

After investigation of the matter, the complaint has been classified as:	<input type="checkbox"/> MAJOR <input checked="" type="checkbox"/> MINOR <input type="checkbox"/> CRITICAL
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ACTION REQUIRED

SR. NO.	RESPONSIBLE PARTY	ACTION TO BE TAKEN	TIME FRAME
1.	Distributor	Immediately stop sale and distribution of Batch No. KT-071.	Immediate
2.	Distributor	Inform all customers/end users who have received the affected batch.	Within 48 Hours
3.	Distributor	Return available stock and provide quantitative details of recalled units to the manufacturer.	Within 7 Days

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4.	End User	Immediately discontinue the use of the affected batch, segregate all available stock, and return any unused products through the respective distributor.	Within 48 Hours
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POSSIBLE ADVERSE EFFECTS IF ACTION IS NOT TAKEN

SR. NO.	RESPONSIBLE PARTY	POSSIBLE ADVERSE EFFECTS
1.	End User	Potential risk of infection
2.	Distributor	Regulatory non-compliance and continued market circulation of affected products.

STATUS OF INVESTIGATION

INVESTIGATION STATUS	DETAILS
Current Status	After Investigation
Corrective Action (if any)	-
Expected Closure Date	-

NOTIFICATION

A copy of this Advisory Notice has been forwarded to the following parties:

- All Affected Distributors
- End Users
- Notified Body
- Government Authority
- Others: _____

Authorized Signatory

For **MEDIVISION HEALTH CARE**

NAME	Jagdishkumar Dungardas Patel
DESIGNATION	Partner
SIGN	
DATE	27-06-2026

