



RAPID ALERT

DRAP ALERT NO. N° I/S/08-23-31

UNREGISTERED INTRAVENOUS MEDICAL DEVICES IN THE MARKET (IV CANNULAS, SYRINGES, INFUSION SETS ETC.)

Date: 10th August 2023

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- General Public.

Problem Statement:

The Medical Device Rules 2017 provides the regulatory framework for medical devices in the country. SRO 224(I)/2023 dated 27-02-2023 provides a transition period for the registration of medical devices to licensed importers and manufacturers as per risk-based classifications. However, medical devices specified in Schedule-E of this SRO are mandatory to be registered with DRAP before marketing in the country. DRAP has received reports/complaints that some unregistered medical devices (e.g., IV cannulas, infusion sets, syringes, etc.) are being proliferated in the open market. An illustrative picture of such products being reported is attached hereunder).

Affected Products:

As per Annex-I

Risk Statement:

The use of unregistered medical devices poses significant risks to patients as they may not meet the necessary standards of safety, quality, and performance. Such medical devices can be nonsterile, or their sterility can be compromised from damage during shipping and storage. The hazards associated with the use of unregistered medical device includes inaccurate or unreliable results, Infection or other adverse reactions, Failure of the device's intended purpose, and Injury or death.



DRAP, Islamabad



92 51 9107404



addl-dir.qa@dra.gov.pk



Actions Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health facilities (Hospitals) in addition to markets and confiscate these products where available. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying these products. Any remaining stock should be quarantined immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) in order to ensure the removal of these unregistered products.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these products. Procurement staff in healthcare settings must obtain the registration status of medical devices falling in schedules D and E of the Medical Device Rules, 2017, from the suppliers. It's imperative to note that authorized manufacturers and importers hold the exclusive right to provide medical devices in the market.

Adverse reactions or quality problems experienced with the use of these products shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using [Adverse Event Reporting Form](#) or online through this [link](#). Further information of reporting problems to DRAP is available on this [link](#).

Advice for Consumers / General Public: -

Consumers should stop using this product and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product and report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be bought from licensed pharmacies or authorized retail outlets. It is important to verify the authenticity and condition of products and seek advice from your pharmacist or healthcare professionals if there are any concerns.



Drug Regulatory Authority of Pakistan

محفوظ، موثر اور معیاری اشیائے علاج



DRAP, Islamabad



92 51 9107404



addl-dir.qa@dra.gov.pk

Annex-I

Sr.	Product Name	Manufacturer / Importer as per label	Illustration
1.	Euro Plus Infusion Set	Apex Medical Devices	
2.	Chiron Infusion Set	Not mentioned	
3.	Health Plus Infusion Set	Not mentioned	
4.	O'Divine Infusion Set	Not mentioned	
5.	Cath-Tec I.V Cannula	Nilhol Enterprises East Lane Business Park Wemby, UK	
6.	Healthflon I.V. Cannula	Healthylife medical equipment Trading, Alfajar Business Centre, airport road, Dubai, UAE	

