# DRUG REGULATORY AUTHORITY OF PAKISTAN
## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/10-26-42

## MEDICAL DEVICES DECLARED SUBSTANDARD BY PROVINCIAL LABORATORIES

**Date:** 20th October, 2026

**Target Audience:**

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

**Alert Summary:**

Drug Testing Laboratory, Lahore has informed Drug Regulatory Authority of Pakistan that samples of the below-mentioned medical devices have been declared **"Substandard"** on the basis of sterility testing and **"Misbranded"** on the basis of labelling as two needle gauges are mentioned on label.

| S# | Product Name | Manufacturer / Importer & Address | Batch No. | Remarks |
|---|---|---|---|---|
| 1 | CLINIC Disposable Syringes 20mL | M/s SURGI PLAST Plot # 78, Road no. L-4, Industrial Estate Gadoon Amazai, KPK. (ELM-0030) | 20-01G-25 | The sample is SUBSTANDARD on the basis of Sterility test and MISBRANDED on the basis of labelling as two needle gauges are mentioned on label. |

**Risk Statement:**

The syringes may pose a risk of infection or other harm because they failed sterility testing. The label also lists two different gauges, which may lead to selection or use of the wrong syringe size. The use of a non-sterile syringe could introduce microorganisms into the patient, potentially causing local or systemic infection. The conflicting gauge information may also result in incorrect device selection, affecting the intended procedure or medication delivery.

**Action initiated: -**

The field force of DRAP and Provincial Drug Control Departments has been directed to immediately conduct market surveys for detection of presence and removal of the affected batches from the market. Manufacturer and distributors have been directed to initiate recall of the affected batches in accordance with applicable regulatory requirements.

**Advice for Pharmacies/Medical stores: -**

All pharmacists and chemists working at distributions and pharmacies should immediately check their stocks and stop supplying the above-mentioned batches. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units should also increase surveillance in the market to ensure effective recall of the affected products.

**Advice for Healthcare Professionals: -**

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by the above-mentioned batch the product. Adverse reactions or quality problems experienced with the use of above-mentioned batch of the drug product are to 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 and healthcare facilities in possession of the above-mentioned batch should immediately stop using these products and contact the supplier, distributor or manufacturer for return or replacement. Any adverse event or quality issue associated with the use of these products should be reported to DRAP/National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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