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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/10-26-46

MEDICAL DEVICES DECLARED SUBSTANDARD BY DRUG TESTING LABORATORY PUNJAB, Rawalpindi

Date: 23rd 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 (DTL) of Punjab Province informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturer/Importer	Remarks
1.	**CIKINA Umbilical Cord Clamp** (Umbilical Cord Clamp (Sterile Device) (MDIR # 0003486)	25495	M/s Ningbo Greatcare Trading Co. Ltd, China; Marketed by Al-Hamd Enterprises, FL-11/1/1, Block 6, Gulshan e Iqbal Karachi Karachi (ELI # 00285)	The sample is declared as **Substandard** on the basis of sterility testing by Drug Testing Laboratory Punjab, Rawalpindi.

Risk Statement:

The sterility failure of the umbilical cord clamp may result in exposure of neonatal patients to microbial contamination. Due to the vulnerable patient population, inability of the user to detect the defect, and potential for serious infection including sepsis, the residual risk is considered unacceptable and requires immediate corrective and regulatory action.

Action initiated: -

The Provincial Drug Control departments and DRAP's field offices have been asked to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned 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 should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using the drug products and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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