Government of India
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Diagnostics Division)
FDA Bhawan, Kotla Road, New Delhi-110002

File No. IVD/BG Sera/ NSQ/ 001/2017-DC

Dated, 15 SEP 2017

PUBLIC NOTICE

Subject: Report of test / analysis of **Mediclone D (Blood Grouping Sera Anti-D) B. No. 88BG022** from the Govt. Analyst, NIB (NOIDA) declaring Not of Standard Quality under Drugs and cosmetics Act 1940 and Rules thereof -Regarding

This office has received Certificate of test / analysis (in Form 13) from the Government analyst at Blood Reagents laboratory, National Institute of Biological (NOIDA), under Section 25(1) of The Drugs and Cosmetics Act, 1940 and Rule-46 of Drugs and Cosmetics Rules, 1945 for the below mentioned products manufactured by M/s. Mediclone Biotech Pvt .Ltd. 29 Biopavilion, Velichai, Chennai-600048. The samples of the said product was drawn by the Drugs Inspector, Jalgaon (Maharashtra) and forwarded to NIB, Noida for Testing. The govt. analyst at NIB (NOIDA) has now declared the following products as Not of Standard Quality (NSQ) under the provisions of Drugs and Cosmetics Act, 1940. The details are given below

Sl. No.	Name of Product / Batch / Lot No./ Mfg. date	Analytical report	Remark
1	**Mediclone –D** (Blood Grouping sera, Anti-D) B. No. 88BG022 Mfg. date ; 07-2016 Exp. Date : 06-2018	N/GA-03/2017-18/BRL/21 Dated 16-08-2017	Sample declared as **Not of Standard Quality**

The general public is hereby notified that the above mentioned Blood Grouping Sera of the said batch should not be used in any form.

(Dr. S. Eswara Reddy)
Joint Drugs Controller (India)

Copy to,
1. All State Drugs Controllers
2. All Zonal and Sub Zonal Offices of CDSCO.
3. Director, NIB, NOIDA, UP
4. CDSCO Web site.