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மருத்துவ ஆராய்ச்சி நிறுவனம்
MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA



National Control Laboratory – Lot Release Certificate

Examined under the gazette notification No.1052/3 of 02/11/1998 and according to the section 137 (2) of National Medicines Regulatory Authority Act No. 5 of 2015.

Name of the vaccine/serum	BCG Vaccine Live Attenuated (Freeze-Dried)
Trade name	Same as above
Name and address of manufacturer	Serum Institute of India Pvt. Ltd., India
Name and address of sample sender	Chief Epidemiologist Epidemiology Unit Colombo 10
Sample sender's reference and date	Documents & samples submitted on 20.02.2026
Type of container	Vial (1mL)
Number of doses per container	20 (0.05 mL/dose)
Prescribed storage temperature	2°C -8°C

Lot No	Mfg. Date	Exp. Date	No of containers released
0375MA029	July 2025	June 2027	21,450 vials

This vaccine / serum lot is in compliance with the specifications approved in the marketing authorization and all national and relevant WHO requirements*, and is released.

This examination is based on

- the review of the manufacturing and testing protocols
 the appropriate control laboratory tests as indicated in the vaccine testing policy

Certificate No: 06/2026/LR	Date of issue: 20.02.2026
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Signature:

Dr. Muthugala M.A.R.V.
MBBS, Pg Dip. Med Micro. Dip R & DP, MD (Virology)
Consultant Medical Virologist
Medical Research Institute
Colombo 08.

Name and designation of authorized signatory: Dr. M.A.R.V. Muthugala, Head / NCL

* WHO Technical Report Series No 986, Annex 2, 2014; WHO Technical Report Series No 999, Annex 2, 2016;
WHO Technical Report Series No 978, Annex 2, 2013; WHO Technical Report Series No 979, Annex 3, 2013.

Copy to – CEO, National Medicines Regulatory Authority