

1504 София, бул. Янко Сакъзов 26
 Факс: **359 2 943 34 55
 Телефон Управител:
 **359 2 944 61 91
 e-mail: bulbio@bulbio.com

1504 Sofia, 26 Yanko Sakazov blvd.
 Fax: **359 2 943 34 55
 Telephone General Manager:
 **359 2 944 61 91
 e-mail: bulbio@bulbio.com

CERTIFICATE

№ 25 / 05.02.2016
For Quality Control of BCG Vaccine
Freeze-dried

1. Name and Address of manufacturer: BB - NCIPD Ltd
 26, Yanko Sakazov, 1504,
 Sofia, Bulgaria
2. Lot number and size of the Lot: 203 15 020 amp
3. Date of manufacture of the lot: February 2016
4. Containers: Vacuum ampoules containing
 10 Doses / 20 Infant
5. Appearance / color
 - freeze-dried vaccine dry powder / whitish color
 - reconstituted vaccine homogenous, slightly pale
 suspension
6. Identity test (stained smears,
 growth on Lowenstein-Jensen): Approved
7. Test for absence of contaminating
 microorganisms (WHO): Approved
8. Test for absence of virulent
 Mycobacteria (WHO): Approved
9. Test for total bacterial content (Opacity): 0.328 Approved
10. Test for Number of Culturable Particles (NCP):
 Method of determination: WHO/TB/Techn.Guide/77.9
 Medium: Lowenstein-Jensen
 No of container tested: six
 Date of the last satisfactory test: 28.03.2016
 NCP: 4.8 x 10⁶ / ml
11. Test for thermostability: 25.00 % Approved
12. Moisture content /Not more than 3,0 per cent/ 0.011 %
 /Loss on drying/ Date of performing the test 07.03.2016
13. Vacuum test: Approved
14. Expiry date: February 2019
15. Storage temperature from +2 °C to +8 °C

Date of issue: 01.06.2016

Head of Quality Control Department: 

I.J. Cenkova, MD/

