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**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:** 202 - 1      15 000 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):** 0.333      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: 25.03.2016  
 NCP: 4.6 x 10<sup>6</sup> / ml
11. **Test for thermostability:** 23.91 %      Approved
12. **Moisture content /Not more than 3,0 per cent/** 0.012 %  
 /Loss on drying/      Date of performing the test 01.03.2016
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: 

/J. Cenkova, MD/

Without Validity October 2018