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**CERTIFICATE**

№ 57 / 12.05.2017  
 For Quality Control of BCG Vaccine  
 Freeze-dried

- |   |   |
|---|---|
| 1. Name and Address of manufacturer:  | BB - NCIPD Ltd<br>26, Yanko Sakazov, 1504,<br>Sofia, Bulgaria         |
| 2. Lot number and size of the Lot:  | 295 - 2                      14 900 amp                               |
| 3. Date of manufacture of the lot:  | February 2017   |
| 4. Containers:  | Vacuum ampoules containing<br>10 Doses / 20 Infant                    |
| 5. Appearance / color   | dry powder / whitish color<br>homogenous, slightly pale<br>suspension |
| - freeze-dried vaccine  |   |
| - reconstituted vaccine   |   |
| 6. Identity test (stained smears,<br>growth on Lowenstein-Jensen):  | Approved  |
| 7. Test for absence of contaminating<br>microorganisms (WHO):   | Approved  |
| 8. Test for absence of virulent<br>Mycobacteria (WHO):  | Approved  |
| 9. Test for total bacterial content (Opacity):  | 0.397                      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:   | 22.03.2017  |
| NCP   | 4.5 x 10 <sup>5</sup> / ml  |
| 11. Test for thermostability:   | 24.44 %                      Approved                                 |
| 12. Moisture content /Not more than 3,0 per cent/<br>/ Loss on drying/                      Date of performing the test | 0.011 %<br>22.02.2017   |
| 13. Vacuum test:  | Approved  |
| 14. Expiry date:  | February 2020   |
| 15. Storage temperature   | from +2 °C to +8 °C   |

Head of Quality Control Department:

*I.J. CenKova, MD/*

Date of issue: 12.05.2017

Without WMI October 2018