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**CERTIFICATE**

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

- |  |   |
|--|---|
| <b>1. Name and Address of manufacturer:</b>                            | BB - NCIPD Ltd<br>26, Yanko Sakazov, 1504,<br>Sofia, Bulgaria |
| <b>2. Lot number and size of the Lot:</b>                              | 204 - 1                      15 080 amp                       |
| <b>3. Date of manufacture of the lot:</b>                              | February 2016   |
| <b>4. Containers:</b>  | Vacuum ampoules containing<br>10 Doses / 20 Infant            |
| <b>5. Appearance / color</b>   |   |
| - freeze-dried vaccine   | dry powder / whitish color                                    |
| - reconstituted vaccine suspension                                     | homogenous, slightly pale                                     |
| <b>6. Identity test (stained smears, growth on Lowenstein-Jensen):</b> | Approved  |
| <b>7. Test for absence of contaminating microorganisms (WHO):</b>      | Approved  |
| <b>8. Test for absence of virulent Mycobacteria (WHO):</b>             | Approved  |
| <b>9. Test for total bacterial content (Opacity):</b>                  | 0.336                      Approved                           |
| <b>10. Test for Number of Culturable Particles (NCP):</b>              |   |
| Method of determination: WHO/TB/Techn.Guide/77.9                       |   |
| Medium: Lowenstein-Jensen  |   |
| No of container tested:  | six   |
| Date of the last satisfactory test:                                    | 30.03.2016  |
| NCP:   | 4.6 x 10 <sup>6</sup> / ml                                    |
| <b>11. Test for thermostability:</b>                                   | 23.91 %                      Approved                         |
| <b>12. Moisture content /Not more than 3,0 per cent/</b>               | 0.010 %   |
| /Loss on drying/                      Date of performing the test      | 08.03.2016  |
| <b>13. Vacuum test:</b>  | Approved  |
| <b>14. Expiry date:</b>  | February 2019   |
| <b>15. Storage temperature</b>   | from +2 °C to +8 °C   |

Date of issue: 01.06.2016

Head of Quality Control Department:   
 /J. Cenkova, MD/