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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>                            | <b>BB - NCIPD Ltd</b><br>26, Yanko Sakazov, 1504,<br>Sofia, Bulgaria |
| <b>2. Lot number and size of the Lot:</b>                              | <b>175 - 2                      15 060 amp</b>                       |
| <b>3. Date of manufacture of the lot:</b>                              | November 2015  |
| <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>                  | 0.332                      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:                                    | 18.12.2015   |
| NCP:   | 4.7 x 10 <sup>6</sup> / ml   |
| <b>11. Test for thermostability:</b>                                   | 23.40 %                      Approved                                |
| <b>12. Moisture content</b> /Not more than 3,0 per cent/               | 0.011 %  |
| /Loss on drying/                      Date of performing the test      | 20.11.2015   |
| <b>13. Vacuum test:</b>  | Approved   |
| <b>14. Expiry date:</b>  | November 2018  |
| <b>15. Storage temperature</b>   | from +2 °C to +8 °C  |

**Head of Quality Control Department:**

*I.J. Cenkova, MD/*

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Withdrawn October 2018