

## CERTIFICATE OF ANALYSIS

Product: **CLOTEID 4, suspensie injectabilă**

Batch No.: **646227A**

Expiry: **8.12.2023**

Date of production: **9.12.2020**

### Results of analysis:

| Tests                           | Release limits                                                                                                                                                                                                           | Shelf-life limits | Results      |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|
| Appearance                      | Gray-white up to grey-brown suspension, without rough inshakeable particles. Standing is created shakeable sediment.                                                                                                     |                   | conforms     |
| Content of the original package | min. 1, 5, 10, 20 ml                                                                                                                                                                                                     |                   | 1 ml         |
| Sterility                       | Vaccine must be sterile.                                                                                                                                                                                                 |                   | sterile      |
| Residual toxicity               | Complies with Eu. Pharm. in law, 5 guinea pigs (350 – 450 g) are subcutaneously administered by 5 ml of the vaccine. No animal has symptoms of disease or die of causes attributed to the vaccine. Vaccine must be safe. |                   | conforms     |
| Identity and efficacy           | Complies with Eu. Pharm. in law, min.30 IU/ml. Vaccine must be efficient.                                                                                                                                                |                   | 32 IU/ml     |
| Content of aluminum oxide       | 1.5 – 3.0 mg/ml                                                                                                                                                                                                          |                   | 1.5 mg/ml    |
| Thiomersal content              | 0.15 mg/ml (0.1275 – 0.1725 mg/ml)                                                                                                                                                                                       |                   | 0.1620 mg/ml |
| pH                              | 6.8 – 8.0                                                                                                                                                                                                                |                   | 7.7          |
| Air tightness                   | The vials must be hermetically sealed.                                                                                                                                                                                   |                   | conforms     |

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 341.



  
.....22/2/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP