

## CERTIFICATE OF ANALYSIS

Product: **BoviBio Respi 4, suspensie injectabilă**

Batch No.: **885927A**

Expiry: **20.9.2022**

Date of production: **21.9.2020**

### Results of analysis:

| Tests                       | Release limits                                                                          | Shelf-life limits | Results                    |
|-----------------------------|-----------------------------------------------------------------------------------------|-------------------|----------------------------|
| Appearance                  | Rosy liquid with sediment.                                                              |                   | conforms                   |
| Content of original package | min. 2 ml, 10 ml, 20 ml, 50 ml, 100 ml                                                  |                   | 10.2 ml                    |
| Sterility                   | The vaccine must be sterile.                                                            |                   | sterile                    |
| Inactivation                | Every antigen must be inactivated.                                                      |                   | conforms                   |
| Efficacy                    | The vaccine must be efficient.                                                          |                   | conforms                   |
| Identity                    | The vaccine stimulates the production of specific antibodies against declared antigens. |                   | conforms                   |
| pH                          | 6.5 – 7.5                                                                               |                   | 7.4                        |
| Bacterial endotoxins        | max. $5.72 \times 10^4$ EU/vaccination dose (2 ml)                                      |                   | $1.79 \times 10^4$ IU/v.d. |
| Aluminium oxide content     | 0.2 – 0.6 %                                                                             |                   | 0.3 %                      |
| Formaldehyde content        | max. 0.05 %                                                                             |                   | 0.003 %                    |
| Thiomersal content          | 0.1 mg / ml (0.085 – 0.115)                                                             |                   | 0.096 mg /ml               |
| Air tightness               | The vials must be closed hermetically                                                   |                   | 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. 190.

.....4/11/2020  
Mgr. Hana Nezvalová  
HEAD of QC, QP

