

## CERTIFICATE OF ANALYSIS

Product: **SERGON 1000 UI, liofilizat și solvent pentru soluție injectabilă**

Batch No.: **946027A**

Expiry: **13.10.2022**

Date of production: **14.10.2020**

**Results of analysis:**

| Tests                                 | Release limits                                                                                          | Shelf-life limits | Results            |
|---------------------------------------|---------------------------------------------------------------------------------------------------------|-------------------|--------------------|
| Appearance                            | Greyish white to greyish blue lyophilizate, after dissolving a clear or opalescent green-blue solution. |                   | conforms           |
| Sterility                             | The product shall be sterile.                                                                           |                   | sterile            |
| Identity of active substance          | Enlargement of ovary weight.                                                                            |                   | conforms           |
| Efficacy of active substance          | 375 – 650 IU/ml<br>Efficacy of serum gonadotropin shall range between 75 % and 130 %.                   |                   | 504 IU/ml<br>101 % |
| Identity of methylparahydroxybenzoate | Must comply.                                                                                            |                   | conforms           |
| Methylparahydroxybenzoate content     | 1.62 – 1.98 mg/ml                                                                                       |                   | 1.84 mg/ml         |
| Identity of propylparahydroxybenzoate | Must comply.                                                                                            |                   | conforms           |
| Propylparahydroxybenzoate content     | 0.18 – 0.22 mg/ml                                                                                       |                   | 0.22 mg/ml         |
| pH                                    | 7.0 – 8.0                                                                                               |                   | 7.5                |
| Vacuum                                | Max 2.66 Pa.                                                                                            |                   | conforms           |
| Residual humidity                     | max. 5.0 %                                                                                              |                   | 1.0 %              |
| Safety test                           | The product conforms to the test if no mouse will perish within 24 hours.                               |                   | conforms           |

**Diluent**

| Tests              | Release limits                     | Shelf-life limits | Results  |
|--------------------|------------------------------------|-------------------|----------|
| Appearance         | Clear colourless solution.         |                   | conforms |
| pH                 | 6.5 – 7.8                          |                   | 7.5      |
| Extractable volume | min. 2 ml                          |                   | 2.1 ml   |
| Airtightness       | The vials must be airtight sealed. |                   | conforms |
| Sterility test     | The preparation must be sterile.   |                   | sterile  |

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. 200.



  
 .....9/12/2020  
 Mgr. Hana Nezvalová  
 HEAD of QC, QP