

|         |                                                                       |                            |                                                          |
|---------|-----------------------------------------------------------------------|----------------------------|----------------------------------------------------------|
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QCZD755SDX3210

## ANALYSIS CERTIFICATE

|                  |                                   |
|------------------|-----------------------------------|
| Product          | CANVAC R suspension for injection |
| Batch No.        | 191221D                           |
| Volume           | 200 packs 60 x 1 dose Romania     |
| Manufacture Date | 2021-12-07                        |
| Expiry Date      | 11/2023                           |

**Appearance:** White or pink liquid containing readily dispersible sediment.

**Packing size:** 1 ml of product in the glass vial.

| Tests                          |                                                      |                               |
|--------------------------------|------------------------------------------------------|-------------------------------|
| Analysis                       | Specification                                        | Results                       |
| Utilizable volume              | Utilizable volume must be higher than nominal volume | Passed                        |
| Content of thiomersal          | NMT 0.010 %                                          | 0.005 %                       |
| pH volume                      | 7.20 to 8.20                                         | 7.47                          |
| Content of aluminium hydroxide | 1.40 – 6.50 mg.ml <sup>-1</sup>                      | 5.59 mg.ml <sup>-1</sup>      |
| Airtightness                   | The vials must be airtight closed                    | Passed                        |
| Sterility (bacteria and fungi) | The product must be sterile                          | Passed                        |
| Residual live virus            | Residual live virus must not be proved               | Passed                        |
| Identity                       | Identity must be proved                              | Passed                        |
| Efficacy - serology            | Potency of testing batch > 2 IU/ml, (p<=0,05)        | Passed > 2 IU/ml<br>p = 0,035 |

|               |            |            |         |
|---------------|------------|------------|---------|
| Date of Issue | 2022-02-18 | Valid till | 11/2023 |
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