

QUALITY CERTIFICATE Certificate of Analysis (CoA)

Ref: 3990210 (Former: 14363S)- Syringe NaCl 0,9%, Luer Lock, 10 ml

Batch: 2412052

Expiry date: 2027-10

The following data are related to the sodium chloride (NaCl) 0,9% solution:

| Tests: | Specifications: | Results per batch: | |
|----------------------|-------------------|--------------------|----------------|
| | | 2410004 | 2410039 |
| pH | 4.5 – 7.0 | 6.3 | 6.3 |
| Iron | <1 ppm | <0.04 ppm | <0.04 ppm |
| Heavy metals | <1 ppm | <0.04 ppm | <0.04 ppm |
| Bacterial Endotoxins | < 0.5 EU/mL | <0.5 EU/mL | <0.5 EU/mL |
| NaCl Concentration | 0.86-0.95 g/100mL | 0.91 g/ 100ml | 0.91 g/ 100ml |

The following data are related to the prefilled syringes testing:

| Tests: | Specifications: | Results per batch: |
|--------------------|-----------------|--------------------|
| | | 2410131 |
| Clarity | Transparent | Complies |
| Colour | Colourless | Complies |
| Extractable volume | ≥ 10.00 mL | 10.18 mL |

The following data are related to the prefilled syringes final release testing:

| Tests: | Specifications: | Result |
|----------------------|-----------------|------------|
| Bacterial Endotoxins | < 0.5 EU/mL | <0.5 EU/mL |

The above mentioned product prefilled syringe NaCl 0,9% has been manufactured by Sterisets Manufacturing S.A. and complies with the specifications for batch release according to IMP 214 and IMP 075.

Quality Department

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21/01/2025

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