

## QUALITY CERTIFICATE Certificate of Analysis (CoA)

**Ref:** 3990110 (Former: 14363SNS)- Syringe NaCl 0,9%, Luer Lock, 10 ml SNS

**Batch:** 2501007

**Expiry date:** 2027-11

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

| Tests:               | Specifications:   | Results per batch: |               |               |
|----------------------|-------------------|--------------------|---------------|---------------|
|                      |                   | 2410173-1          | 2410173-2     | 2410175-2     |
| pH                   | 4.5 – 7.0         | 6.0                | 5.6           | 5.9           |
| Iron                 | <1 ppm            | <0.04 ppm          | <0.04 ppm     | <0.04 ppm     |
| Heavy metals         | <1 ppm            | <0.04 ppm          | <0.04 ppm     | <0.04 ppm     |
| Bacterial Endotoxins | < 0.5 EU/mL       | <0.5 EU/mL         | <0.5 EU/mL    | <0.5 EU/mL    |
| NaCl Concentration   | 0.86-0.95 g/100mL | 0.94 g/ 100ml      | 0.89 g/ 100ml | 0.93 g/ 100ml |

| Tests:               | Specifications:   | Results per batch: |               |               |
|----------------------|-------------------|--------------------|---------------|---------------|
|                      |                   | 2410238-1          | 2410238-2     | 2410239-1     |
| pH                   | 4.5 – 7.0         | 6.1                | 6.0           | 6.0           |
| Iron                 | <1 ppm            | <0.04 ppm          | <0.04 ppm     | <0.04 ppm     |
| Heavy metals         | <1 ppm            | <0.04 ppm          | <0.04 ppm     | <0.04 ppm     |
| Bacterial Endotoxins | < 0.5 EU/mL       | <0.5 EU/mL         | <0.5 EU/mL    | <0.5 EU/mL    |
| NaCl Concentration   | 0.86-0.95 g/100mL | 0.93 g/ 100ml      | 0.91 g/ 100ml | 0.93 g/ 100ml |

The following data are related to the prefilled syringes testing:

| Tests:             | Specifications: | Results per batch: |          |          |
|--------------------|-----------------|--------------------|----------|----------|
|                    |                 | 2411065            | 2411082  | 2411083  |
| Clarity            | Transparent     | Complies           | Complies | Complies |
| Colour             | Colourless      | Complies           | Complies | Complies |
| Extractable volume | ≥ 10.00 mL      | 10.16 mL           | 10.22 mL | 10.21 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 |

**Sterisets Manufacturing S.A.**

Zona Industrial 1 – Lote 34 a 35, 4560-164 Guilhufe, Penafiel PORTUGAL

Phone: +31 412 236 606

[www.sterisets.com](http://www.sterisets.com)

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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**

*Joana Pinto*

12/02/2025

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