

## QUALITY CERTIFICATE Certificate of Analysis (CoA)

**Ref:** 3020010 - Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – fill 10 ml

**Batch:** 2501122

**Expiry date:** 2027-11

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

Tests:	Specifications:	Results per batch:			
		2410174-1	2410174-2	2410240-1	2410240-2
pH	4.5 – 7.0	5.9	5.9	5.8	5.7
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.04 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	<0.5 EU/mL
NaCl Concentration	0.86-0.95 g/100mL	0.94 g/ 100ml	0.89 g/ 100ml	0.94 g/ 100ml	0.93 g/ 100ml

Tests:	Specifications:	Results per batch:		
		2410239-2	2410241-1	2410241-2
pH	4.5 – 7.0	5.9	5.9	6.1
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	0.94 g/ 100ml	0.92 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:			
		2411066	2411086	2411087	2411165
Clarity	Transparent	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies
Extractable volume	≥ 10.00 mL	10.14 mL	10.13 mL	10.23 mL	10.13 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.**

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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*

06/02/2025