

## QUALITY CERTIFICATE Certificate of Analysis (CoA)

**Ref:** 3020012 - Syringe Water with NaCl 0,9%, Luer Lock, 20 ml (fill 20ml)

**Batch:** 2501121

**Expiry date:** 2027-01

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

Tests:	Specifications:	Results per batch:		
		2410175-1	2410175-2	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	0.93 g/ 100ml	0.92 g/ 100ml

Tests:	Specifications:	Results per batch:		
		2411006-1	2411061-2	2411096-1
pH	4.5 – 7.0	5.9	6.4	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	0.93 g/ 100ml	0.92 g/ 100ml	0.93 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:				
		2411084	2411085	2411186	2411187	2412021
Clarity	Transparent	Complies	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies	Complies
Extractable volume	≥ 20.00 mL	20.37 mL	20.52 mL	20.40 mL	20.24 mL	20.23 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