

## QUALITY CERTIFICATE

### Certificate of Analysis (CoA)

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

**Batch:** 2409134

**Expiry date:** 2027-07

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

Tests:	Specifications:	Results per batch:		
		2406045	2406047	2406048
pH	4.5 – 7.0	6.2	6.2	6.2
Iron	<1 ppm	<0.04 ppm	<0.2 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.2 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	0.92 g/ 100ml	0.94 g/ 100ml	0.94 g/ 100ml

Tests:	Specifications:	Results per batch:	
		2406101	2406144
pH	4.5 – 7.0	6.5	6.2
Iron	<1 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.2 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	0.90 g/ 100ml	0.90 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:				
		2407010	2407061	2407081	2407082	2407130
Clarity	Transparent	Complies	Complies	Complies	Complies	Complies
Colour	Colourless	Complies	Complies	Complies	Complies	Complies
Extractable volume	≥ 20.00 mL	20.39 mL	20.31 mL	20.34 mL	20.37 mL	20.20 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*

22/01/2025