

QUALITY CERTIFICATE Certificate of Analysis (CoA)

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

Batch: 2412100

Expiry date: 2027-10

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

Tests:	Specifications:	Results per batch:			
		2409188	2410039	2410040-1	2410041-1
pH	4.5 – 7.0	6.1	6.3	6.2	6.3
Iron	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.2 ppm
Heavy metals	<1 ppm	<0.04 ppm	<0.04 ppm	<0.04 ppm	<0.2 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	0.93 g/ 100ml	0.91 g/ 100ml	0.93 g/ 100ml	0.90 g/ 100ml

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:	
		2410107	2410134
Clarity	Transparent	Complies	Complies
Colour	Colourless	Complies	Complies
Extractable volume	≥ 10.00 mL	10.19 mL	10.17 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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