

QUALITY CERTIFICATE

Certificate of Analysis (CoA)

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

Batch: 2411004 **Expiry date:** 2027-09

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

Tests:	Specifications:	Results per batch:	
		2409021	2409022
рН	4.5 – 7.0	6.3	6.2
Iron	<1 ppm	<0.04 ppm	<0.04 ppm
Heavy metals	<1 ppm	<0.2 ppm	<0.2 ppm
Bacterial Endotoxins	< 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

The following data are related to the prefilled syringes testing:

Tests:	Specifications:	Results per batch:	
		2409145	
Clarity	Transparent	Complies	
Colour	Colourless	Complies	
Extractable volume	≥ 10.00 mL	10.16 mL	

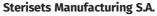
The following data are related to the prefilled syringes final release testing:

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

Joana Pinto 17/12/2024



Zona Industrial 1 – Lote 34 a 35, 4560-164 Guilhufe, Penafiel PORTUGAL Phone: +31 412 236 606 www.sterisets.com

