

Manufacturer:	Sterisets Manufacturing S.A. Zona Industrial 1 – Lote 11 a 14 4560-164 Guilhufe – Penafiel Portugal Phone: +31 412 236 606 Email info@sterisets.com www.sterisets.com
SRN:	PT-MF-000002822
Product category:	Pre-filled syringes with sodium chloride
Product variants:	
<u>Designation:</u>	<u>Intended purpose:</u>
Syringes with 0.9% sodium chloride	Flushing only vascular access devices
Risk classification:	According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices - Class IIa
Rule:	2
Conformity assessment route:	Annex IX
Common specifications:	Not applicable
EU certificate no.:	2268369CE01
ISO 13485 certificate no.:	2153004
Notified Body:	DEKRA Certification B.V. (ID no 0344)
CE marking:	CE0344

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of Steripack S.A. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

Signature:

Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel, 18-06-2025

To DoC number: DoC2268369CE01

The medical devices which fall under the DoC are:

Product category: Pre-filled syringes with sodium chloride

Product variant: Syringes with 0.9% sodium chloride

Trade name: Sterisets Medical Products

Basic UDI-DI: 5608120PFSNACLO.9IIAV47TJ

REF	Designation
14324BSNS	Syringe NaCl 0,9% Luer 20 ml
14361S	Syringe 5 ml with 0,9% sodium chloride (3ml fill) sterile
14361SNS	Syringe 5 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile
14362S	Syringe 5 ml with 0,9% sodium chloride
14362SNS	Syringe 5 ml with 0,9% sodium chloride sterile/non sterile
14363S	Syringe 10 ml with 0,9% sodium chloride
14363SNS	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile
14364S	Syringe 20 ml with 0,9% sodium chloride
14364SNS	Syringe 20 ml with 0,9% sodium chloride sterile/non sterile
14365S	Syringe 10 ml with 0,9% sodium chloride (3ml fill)
14365SNS	Syringe 10 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile
14366S	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile
14366SNS	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile/non sterile
3010002	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - Fill 3 mL
3010004	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 3 ml
3010006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - Fill 5 ml
3010008	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - Fill 5 ml
3010010	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - Fill 10 ml
3010012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml - Fill 20 ml
3020002	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 3 ml *S
3020004	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml-Fill 3 ml
3020006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml-Fill 5 ml *S
3020008	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml-Fill 5 ml *S
3020010	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml-Fill 10 ml *S
3020012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml-Fill 20 ml *S
3040013	Syringe 20 ml with 0,9% sodium chloride sterile
3040014	Syringe NaCl 0,9% Luer 20 ml

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Product category: Pre-filled syringes with sodium chloride

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Trade name: Sterisets Medical Products

Basic UDI-DI: 5608120PFSNACLO.9IIAV47TJ

REF	Designation
3990110	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile
3990120	Syringe 10 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile
3990125	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile/non sterile
3990170	Syringe NaCl 0,9% Luer Lock 10 ml (butyl + screw) *S
3990203	Syringe NaCl 0,9% Luer Lock 10 ml (3ml fill) *S
3990210	Syringe 10 ml with 0,9% sodium chloride
3990220	Syringe 20 ml with 0,9% sodium chloride

Signature:

Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel, 18-06-2025