

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> Syringes with 0.9% sodium chloride	<u>Intended purpose:</u> 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 Sterisets Manufacturing 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, 15-07-2026

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: 5608120PFSNACL0.9IIAV47TJ

REF	Designation
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
3010002	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 3 ml *S inside only
3010004	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 3 ml *S inside only
3010006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 5 ml *S inside only
3010008	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 5 ml *S inside only
3010010	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 10 ml *S inside only
3010012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml - filling 20 ml *S inside only
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 - filling 3 ml *S
3020006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - filling 5 ml *S
3020008	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 5 ml *S
3020010	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml - filling 10 ml *S
3020012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml - filling 20 ml *S
3040013	Syringe Water with NaCl 0,9%, Luer, 20 ml - Bulk pack *S
3040014	Syringe Water with NaCl 0,9%, Luer, 20 ml *S inside only
3990105	Syringe NaCl 0,9% Luer Lock, 5 ml *S inside only
3990110	Syringe NaCl 0,9% Luer Lock, 10 ml *S inside only
3990115	Syringe NaCl 0,9% Luer Lock, 20 ml *S inside only
3990120	Syringe NaCl 0,9% Luer Lock, 10 ml - 3ml filling *S inside only
3990125	Syringe NaCl 0,9% Luer Lock, 10 ml - 5ml filling *S inside only
3990170	Syringe NaCl 0,9% Luer Lock, 10 ml (butyl + screw) *S
3990203	Syringe NaCl 0,9% Luer Lock, 10 ml - 3ml filling *S
3990205	Syringe NaCl 0,9% Luer Lock, 5 ml *S
3990206	Syringe NaCl 0,9% Luer Lock, 10 ml - 5ml filling *S
3990210	Syringe NaCl 0,9% Luer Lock, 10 ml *S
3990220	Syringe NaCl 0,9% Luer Lock, 20 ml *S

Signature:

Name: Joana Pereira

Function: Management representative

Place and Date: Penafiel, 15-07-2026