

Manufacturer:	Sterisets Manufacturing S.A. Zona Industrial nº 1 – Lote 11 a 14 - 4560-164 Guilhufe – Penafiel, Portugal Tel: +31 412 236 606 Email info@sterisets.com www.sterisets.com
Product category:	Sterile catheterization accessory sets, sterile single use forceps, clamps and scissors, sterile and non sterile dressing sets, sterile dialysis sets, sterile delivery sets, sterile surgical sets, sterile washing sets, sterile and non sterile gauze and non woven swabs and balls and sterile syringes with 0,9% sodium chloride.
Classification:	According to Annex IX of Council Directive 93/42/EEC of 14th June 1993 - Class IIa
Conformity assessment route:	Annex II
CE certificate no.:	2153004CE02
ISO 13485 certificate no.:	2153004
Notified Body:	DEKRA Certification B.V.
CE marking:	CE0344
CE mark was first applied on:	08-09-2012

We hereby declare that the above mentioned medical devices meet the provisions of the Council Directive 93/42/EEC of 14th June 1993 including all subsequent amendments, of the Portuguese Law by Decreto-Lei nº 145/2009 of 17th June, and of the Dutch MDD2007 Besluit Medische Hulpmiddelen. This DoC is valid for the products mentioned on the addendum 1 and addendum 2.

Signature:
Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel, 07-04-2025

To DoC number: DoC2153004CE02

The medical devices which fall under the DoC are:

Product category: Sterile catheterization accessory sets, sterile single use forceps, clamps and scissors, sterile and non sterile dressing sets, sterile dialysis sets, sterile delivery sets, sterile surgical sets, sterile washing sets, sterile and non sterile gauze and non woven swabs and balls and sterile syringes with 0,9% sodium chloride.

REF	Designation
14323S	Syringe 10 ml with 0,9% sodium chloride
14324BSNS	Syringe NaCl 0,9% Luer 20 ml
14324S	Syringe 20 ml with 0,9% sodium chloride sterile
14360S	Syringe 3 ml with 0,9% sodium chloride sterile
14360SNS	Syringe 3 ml with 0,9% sodium chloride sterile/non sterile
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
14363SAL	Syringe NaCl 0,9% Luer Lock 10 ml
14363SNS	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile
14363SNSAL	Syringe NaCl 0,9% Luer Lock 10 ml
14364S	Syringe 20 ml with 0,9% sodium chloride
14364SNS	Syringe 20 ml with 0,9% sodium chloride sterile/non sterile
14365SF	Syringe LL 10 ml NaCl 0,9% (3ml fill) sterile White Cap
14365SNS	Syringe 10 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile
14365SNSF	Syringe LL 10 ml NaCl 0,9% (3ml fill) sterile White Cap
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
15360S	Syringe 3 ml with 0,9% sodium chloride sterile
15362S	Syringe 5 ml with 0,9% sodium chloride
15363S	Syringe 10 ml with 0,9% sodium chloride
15364S	Syringe 20 ml with 0,9% sodium chloride
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
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
3010006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml - Fill 5 ml
3010012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml - Fill 20 ml
3020006	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml-Fill 5 ml *S
3020012	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml-Fill 20 ml *S
3040014	Syringe NaCl 0,9% Luer 20 ml
3040013	Syringe 20 ml with 0,9% sodium chloride sterile
3990210	Syringe 10 ml with 0,9% sodium chloride
3990110	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile
3990220	Syringe 20 ml with 0,9% sodium chloride

To DoC number: DoC2153004CE02

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Product category: Sterile catheterization accessory sets, sterile single use forceps, clamps and scissors, sterile and non sterile dressing sets, sterile dialysis sets, sterile delivery sets, sterile surgical sets, sterile washing sets, sterile and non sterile gauze and non woven swabs and balls and sterile syringes with 0,9% sodium chloride.

REF	Designation
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
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
3020004	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml-Fill 3 ml
3990170	Syringe NaCl 0,9% Luer Lock 10 ml (butyl + screw)

Initial date: 08-09-2012

Signature:

Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel, 07-04-2025