

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 examination gloves, sterile absorbent pads, sterile trays and bowls, sterile syringes with water, sterile syringes with water containing 10% glycerin, sterile surgical drapes, sterile catheterization accessory sets, sterile washing sets, sterile dressing sets and sterile suture accessory sets.
Classification:	According to Annex IX of Council Directive 93/42/EEC of 14th June 1993 - Class I sterile
Conformity assessment route:	Annex II
CE certificate no.:	2153004CE01
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 20-05-2026

To DoC number: DoC2153004CE01

The medical devices which fall under the DoC are:

Product category: Sterile examination gloves, sterile absorbent pads, sterile trays and bowls, sterile syringes with water, sterile syringes with water containing 10% glycerin, sterile surgical drapes, sterile catheterization accessory sets, sterile washing sets, sterile dressing sets and sterile suture accessory sets.

REF	Designation
14313BSNS	Syringe 10 ml with water 10 ml
14313S	Syringe 10 ml with water
14313SNS	Syringe 10 ml with water, sterile/non sterile
14314BSNS	Syringe water Luer 20 ml Bulk
14313BS	Syringe water Luer 10 ml (Film/Paper Bulk)
14314S	Syringe 20 ml with water
14314SNS	Syringe 20 ml with water, sterile/non sterile
14318BSNS	Syringe 10 ml with water 10% glycerine
14318S	Syringe 10 ml with water 10% glycerine
14318BS	Syringe 10 ml with water 10% glycerine
14318SNS	Syringe 10 ml with water with 10% glycerine, sterile/non sterile
3040002	Syringe 10 ml with water
3040006	Syringe water Luer 10 ml Bulk
3040008	Syringe 10 ml with water 10% glycerine
3040010	Syringe 10 ml with water 10% glycerine
3040012	Syringe water Luer 20 ml Bulk
3040017	Syringe Water, Luer, 20 ml - filling 20 ml - Bulk pack *S

Initial date: 08-09-2012

Signature:

Name: Joana Pereira
Function: Management representative
Place and Date: Penafiel 20-05-2026