

Date: 07th October 2025

STATEMENT – PREFILLED SYRINGES (PFS)

To whom it may concern,

We, Sterisets Manufacturing S.A., declare that the medical devices listed in Annex I do not contain:

- Phthalates
- Bisphenols
- Intentionally added microbial agents
- Latex
- Pyrogenic substances
- Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) above 0.1% w/w
- Identified Substances of Very High Concern (SVHC) above 0.1% w/w according to the latest revision of Regulation (EC) nº 1907/2006 – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Substances in a concentration above 0,1% w/w which are carcinogenic, mutagenic or toxic to reproduction (CMR), or having endocrine-disrupting properties, according to section 10.4.1 of Regulation (EU) 2017/745

Please be aware that our suppliers have the commitment to follow Regulation (EC) nº 1907/2006 and to immediately communicate any change to compliance.

Yours sincerely,



Joana Pereira
Quality & Regulatory Affairs Director

Annex I

Product category: Sterile Prefilled Syringes (PFS) with 0,9% sodium chloride

REF	Designation
3040014 (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
3990205 (14362S)	Syringe 5 ml with 0,9% sodium chloride
3990105 (14362SNS)	Syringe 5 ml with 0,9% sodium chloride sterile/non sterile
3990210 (14363S)	Syringe 10 ml with 0,9% sodium chloride
3990110 (14363SNS)	Syringe 10 ml with 0,9% sodium chloride sterile/non sterile
3990220 (14364S)	Syringe 20 ml with 0,9% sodium chloride
3990115 (14364SNS)	Syringe 20 ml with 0,9% sodium chloride sterile/non sterile
3990120 (14365SNS)	Syringe 10 ml with 0,9% sodium chloride (3ml fill) sterile/non sterile
3990206 (14366S)	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile
3990125 (14366SNS)	Syringe 10 ml with 0,9% sodium chloride (5ml fill) sterile/non sterile
3990160	Syringe 3 ml with 0,9% sodium chloride sterile
3010002 (15361SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml – filling 3 ml
3010004 (15365SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 3 ml
3010006 (15362SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml – filling 5 ml
3010008 (15366SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 5 ml
3010010 (15363SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 10 ml
3010012 (15364SNS)	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml – filling 20 ml
3020002 (15361S)	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml – filling 3 ml *S
3020004 (15365S)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 3 ml *S
3020006 (15362S)	Syringe Water with NaCl 0,9%, Luer Lock, 5 ml – filling 5 ml *S
3020008 (15366S)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 5 ml *S
3020010 (15363S)	Syringe Water with NaCl 0,9%, Luer Lock, 10 ml – filling 10 ml *S
3020012 (15364S)	Syringe Water with NaCl 0,9%, Luer Lock, 20 ml – filling 20 ml *S

Product category: Sterile Prefilled Syringes (PFS) with water containing 10% glycerine

REF	Designation
3040016 (14318BSNS)	Syringe 10 ml with water 10% glycerine
3040010 (14318S)	Syringe 10 ml with water 10% glycerine
3040008 (14318BS)	Syringe 10 ml with water 10% glycerine
14318SNS	Syringe 10 ml with water 10% glycerine, sterile/non sterile

Product category: Sterile Prefilled Syringes (PFS) with water

REF	Designation
3040006 (14313BSNS)	Syringe 10 ml with water 10 ml
3040002 (14313S)	Syringe 10 ml with water
14313SNS	Syringe 10 ml with water, sterile non sterile
3040012 (14314BSNS)	Syringe water Luer 20 ml Bulk
3040002 (14313BS)	Syringe 10 ml with water
14314S	Syringe 20 ml with water
14314SNS	Syringe 20 ml with water, sterile/non sterile