Sterisets®
Medical Products

12th October 2026

URGENT: FIELD SAFETY NOTICE

Steriflush Syringes NaCl 0.9%

REF: 14324BSNS, 14362S, 14362SNS, 14363S, 14363SNS, 14364S, 14364SNS, 14365S, 14365SNS, 14366S, 14366SNS, 14361S, 14361SNS, 3010002, 3010004, 3010006, 3010008, 3010010, 3010012, 3020002, 3020004, 3020006, 3020008, 3020010, 3020012, 3040014, 3990110, 3990120, 3990125, 3990170, 3990210, 3990220

Lot Number: all Lots within their expiry date, regardless of Lot number, for the Steriflush references identified in this notice

FSCA-Identifier: 2026/02

Type of Action: Field Safety Corrective Action

This letter contains important information which requires your immediate attention.

Description of the problem:

Sterisets Manufacturing S.A. is conducting a Field Safety Corrective Action (FSCA) involving the collection and return of all unexpired batches of Steriflush remaining available on the market.

This action follows an inspection conducted on 25 September 2025 by INFARMED, I.P., the Portuguese Competent Authority, at the manufacturing facilities of Sterisets Manufacturing S.A.

Based on the findings of this inspection, INFARMED, I.P. determined that the medical devices concerned must be recalled from the market.

Accordingly, Sterisets Manufacturing S.A. is implementing this FSCA in compliance with Resolution No. 095/CD/2026, dated 3 September 2026, issued by the Governing Board of INFARMED, I.P.

Clinical risk:

To date, Sterisets Manufacturing S.A. has not received any reports of serious incidents or product-related adverse events associated with Steriflush.

This FSCA has not been initiated in response to reported serious incidents or identified product-related adverse events but is being implemented following the findings of the inspection and in compliance with the mandatory recall decision issued by INFARMED, I.P.

End Users Actions:

1. Cease use of any affected product - *Steriflush Syringes NaCl 0.9%, REFs 14324BSNS, 14362S, 14362SNS, 14363S, 14363SNS, 14364S, 14364SNS, 14365S, 14365SNS, 14366S, 14366SNS, 14361S, 14361SNS, 3010002, 3010004, 3010006, 3010008, 3010010, 3010012, 3020002, 3020004, 3020006, 3020008, 3020010, 3020012, 3040014, 3990110, 3990120, 3990125, 3990170, 3990210, 3990220, Lot number:* ***all Lots within their expiry date, regardless of Lot number, for the Steriflush references identified in this notice;***
2. Identify and **return** all affected products;

Sterisets Manufacturing S.A.
Zona Industrial 1 – Lote 11 a 14, 4560-164 Guilhufe, Penafiel PORTUGAL
Phone: +31 412 667 755 E-mail: info@sterisets.com
www.sterisets.com

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3. Complete and return the End User Reply Form (Annex A) even if you no longer have any inventory remaining in your facility as soon as possible and no longer than 10 working days;
4. Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred;
5. If you experience any issues, please report as a complaint as per your normal procedure.

Distributor Actions:

1. Cease distribution of any affected product - *Steriflush Syringes NaCl 0.9%, REFs 14324BSNS, 14362S, 14362SNS, 14363S, 14363SNS, 14364S, 14364SNS, 14365S, 14365SNS, 14366S, 14366SNS, 14361S, 14361SNS, 3010002, 3010004, 3010006, 3010008, 3010010, 3010012, 3020002, 3020004, 3020006, 3020008, 3020010, 3020012, 3040014, 3990110, 3990120, 3990125, 3990170, 3990210, 3990220, Lot number:* ***all Lots within their expiry date, regardless of Lot number, for the Steriflush references identified in this notice;***
2. Identify and **return** the affected products;
3. Identify the facilities where you have distributed affected product and notify them immediately of this notice;
    a. Make sure your customers complete and return the appropriate Reply form (Annex A or Annex B) to your organization for reconciliation purposes as soon as possible and no longer than 10 working days;
4. Complete and return the Distributor Reply Form following completion of your reconciliation activities;
5. If you experience any issues, please report as a complaint as per your normal procedure.

Contact reference:

If you have any questions about this, please contact your distributor which will be in contact with us or e-mail QA.PT@sterisets.com.

We confirm that we are informing the appropriate regulatory agencies about these actions.

We kindly ask you to remain attentive to this notice and apologize for any inconvenience it may cause.

Sterisets Manufacturing S.A. remains firmly committed to delivering high-quality products, with patient safety as our foremost priority.

Sincerely,

Joana Pereira

Quality & Regulatory Affairs Director

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Annex A

End User (Hospital/Clinic) Reply Form

Field Safety Notice – FSCA Identifier 2026/02

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Lot Number: all Lots within their expiry date, regardless of Lot number, for the Steriflush references identified in this notice

It is essential that you complete and return this form to enable Sterisets Manufacturing S.A. to finalize the end user notification process.

Please **return the completed form** by email to QA.PT@sterisets.com as soon as possible and **no later than 10 working days.**

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm receipt of the Field Safety Notice and have read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
☐	Affected devices REF: 14324BSNS, 14362S, 14362SNS, 14363S, 14363SNS, 14364S, 14364SNS, 14365S, 14365SNS, 14366S, 14366SNS, 14361S, 14361SNS, 3010002, 3010004, 3010006, 3010008, 3010010, 3010012, 3020002, 3020004, 3020006, 3020008, 3020010, 3020012, 3040014, 3990110, 3990120, 3990125, 3990170, 3990210, 3990220 Lot Number: all Lots within their expiry date, regardless of Lot number, for the Steriflush references identified in this notice, have been returned	Please provide quantity, per Lot number:

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☐	I do not have any affected devices.
Print Name	
Signature	
Date	

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Annex B

Distributor Reply Form

Field Safety Notice – FSCA Identifier 2026/02

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It is essential that you complete and return this form to enable Sterisets Manufacturing S.A. to finalize the distributor notification process.

Please **return the completed form** by email to QA.PT@sterisets.com as soon as possible and **no later than 10 working days.**

Company Name		
Company Address		
Email Address		
Telephone Number		
Name and Job title		
☐	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
☐	I have identified customers that received or may have received this device.	
☐	I have informed the identified customers of this FSN.	Date of communication:
☐	I have received confirmation of reply from all identified customers.	
Print Name		
Signature		
Date		

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