Sterisets®
Medical Products

21th September 2026

URGENT: FIELD SAFETY NOTICE

CitraLock Syringe 4%

REF: 3593S2 **Lot Number:** 2507149, 2509001

FSCA-Identifier: 2026/01

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) to request the **collection and return** of specific lot numbers **2507149 and 2509001** of **CitraLock Syringe 4%**, REF: **3593S2**.

This action follows the previous **FSCA 2025/01**, initiated in relation to reported adverse reactions potentially associated with an earlier batch already recalled of CitraLock Syringe 4%. As part of that FSCA, affected batches manufactured up to batch **2505071** were recalled and additional in-process controls were implemented for subsequent production, including representative hourly sampling to assess batch homogeneity.

The lots subject to the present FSCA, **2507149 and 2509001**, were manufactured following the implementation of these additional controls.

Since implementation of these additional controls, no new incidents involving adverse effects in patients associated with the product have been reported to Sterisets Manufacturing S.A.

Nevertheless, in compliance with **Resolution No. 095/CD/2026 of September 3, 2026, issued by the Governing Board of INFARMED, I.P.**, Sterisets Manufacturing S.A. is proceeding with the collection and return of lots **2507149 and 2509001** from the market.

Clinical risk:

As previously communicated under **FSCA 2025/01**, serious incidents were reported in association with an earlier batch of CitraLock Syringe 4%, with reported symptoms including fever, headaches, tremors, cyanosis of the extremities, and general malaise.

Following those events, additional in-process controls were implemented for subsequent production. Lots **2507149 and 2509001** were manufactured following implementation of these controls, and **no new incidents involving adverse effects in patients associated with the product have been reported to Sterisets Manufacturing S.A. since their implementation**.

Notwithstanding the absence of new reported incidents following implementation of these controls, INFARMED, I.P., following its assessment of the manufacturing conditions and the corrective and preventive actions implemented, **determined that the affected devices should be withdrawn from the market**. Accordingly, in compliance with **Resolution No. 095/CD/2026 of September 3, 2026**, Sterisets Manufacturing S.A. is collecting the affected lots from the market.

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End Users Actions:

1. Cease use of any affected product - *CitraLock Syringe 4%, REF: 3593S2, Lot number:* ***2507149, 2509001;***
2. Identify and **return** all affected products;
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 - *CitraLock Syringe 4%, REF: 3593S2, Lot number:* ***2507149, 2509001;***
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.

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Annex A

End User (Hospital/Clinic) Reply Form

Field Safety Notice – FSCA Identifier 2026/01

CitraLock Syringe 4%, REF: 3593S2, Lot Number: 2507149, 2509001

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: 3593S2, Lot Number: 2507149, 2509001 have been returned	Please provide quantity, per Lot number:
☐	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 2026/01

CitraLock Syringe 4%, REF: 3593S2, Lot Number: 2507149, 2509001

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		