FSCA Ref: CAPA-2026-004
FSN Ref: FSN IRIS PLC software update

Date: May 21, 2026

Urgent Field Safety Notice
IRIS

1. Information on Affected Devices	
1.	Device Type
	Automated injection delivery system for radiopharmaceuticals
2.	Commercial name
	IRIS
3.	Primary clinical purpose of device
	The IRIS is intended to prepare an accurate dose according to the medical prescription, and to perform in bolo intravenous injection for radiotracers for PET diagnostic procedure (Positron Emission Tomography), SPECT (Single Photon Emission Computed Tomography), and radiopharmaceuticals for therapy, providing the protection of the medical personnel from the used radiotracers or radiopharmaceuticals
4.	Device Model/Catalogue/part number
	IRIS / Catalog number:0246010026
5.	Affected range
	Systems with PLC version 2.0.0 and higher

2. Reason for Field Safety Corrective Action (FSCA)

A customer complaint was received reporting the occurrence of a backflow originating from the waste vial.

During the subsequent root cause investigation, it was identified that a backflow from the waste vial towards the manifold could occur during the preparation phase in IRIS systems equipped with PLC software version 2.0.0 and higher. In case a non-sterile waste vial is used and/or the waste vial already contains waste, this backflow is a potential risk of contamination of the manifold.

To address and eliminate this potential risk, a corrective action has been defined in the form of a PLC software update. This update modifies the valve positioning logic to ensure that, in the relevant state, the system does not connect to the waste vial. Instead, the valve position is changed to connect to the patient output line, which is sterile and closed, thereby eliminating any potential contamination pathway.

Although no adverse events or patient harm have been reported to date, this corrective action has been designated as a mandatory Field Safety Corrective Action to ensure continued compliance with the applicable safety and performance requirements.

COMECER

3. Type of Action to mitigate the risk		
1.	Action To Be Taken by the User Install the PLC software version 2.1.3 on the IRIS device Please confirm receipt of this FSN and installation of the PLC software by completing and returning the attached Customer Reply Form.	
2.	By when should the action be completed?	3 months after FSN issuance
3.	Is customer Reply Required?	Yes

4. General Information		
1.	FSN Type	New
2.	Further advice or information already expected in follow-up FSN?	As an immediate risk mitigation measure, if not done already, it is strongly recommended to use an empty sterile waste vial and to replace the waste vial with each main disposable kit change.
3.	For questions or support, please contact: helpdesknl@comecer.com	
4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	

21-5-2026

X

RA van Leeuwen
QA RA Manager

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.