

## FIELD SAFETY NOTICE

### Missing plug

**Macopharma Reference Number:** DEV-2025-00070

**ANSM reference:** R2512755.

Mouvoux, 19<sup>th</sup> of May 2025.

### 1. Identification of the Manufacturer

- **Company name :** MACOPHARMA
- **Contact Information :** [medicaldevice.vigilance@macopharma.com](mailto:medicaldevice.vigilance@macopharma.com)

Dear Sir or Madam,

Macopharma is issuing this letter to inform you of a potential issue with the non-leukoreduced red blood cell collection bag (CV1459) on its inline filtration systems. The affected references and lots are listed in this FSN.

This notification details the issue and provides the necessary actions to be taken by customers.

### 2. Context

Macopharma has been informed of several missing plugs in the non-leukoreduced red blood cell collection bag (CV1459) from batches of LQT reference produced in one of our production plants.

These missing plugs cause a leak detected during the separation of blood components on the press.

This defect is due to a sporadic human error during the device assembly step. An investigation has been launched to implement the necessary corrective and preventive actions in the production plant concerned.

### 3. Affected Product(s) Information

- **Product name :** LQT610L, LQT612U, LQT613E, LQT614E, LQT6280LU, LQT6281LR, LQT6287LU, LQT716C, LQT747C, LQT748C

- **Batch / Lot Number(s):**

BATCH	PRODUCT REFERENCE	COUNTRY
11520961CM	LQT612U	ES-LT
11523588CM	LQT612U	ES
11525832CM	LQT612U	ES
1527133CM	LQT612U	ES-LT
11520120CM	LQT614E	FI-SE
11523224CM	LQT614E	FI
11526672CM	LQT614E	NO
11520975CM	LQT6280LU	HR-IT
11522112CM	LQT6280LU	CZ-HR
11522279CM	LQT6280LU	CZ-HR- CO
11523694CM	LQT6280LU	CZ-FR-HR-IT
11523695CM	LQT6280LU	CZ-FR-IT
11526671CM	LQT6280LU	CY-CZ-SI
11526870CM	LQT6280LU	IT
11527826CM	LQT6280LU	CY
11522280CM	LQT6281LR	IT
11523349CM	LQT6281LR	IT
11524079CM	LQT6281LR	IT
11525950CM	LQT6281LR	IT
11526871CM	LQT6281LR	IT
11528091CM	LQT6281LR	IT
11520949CM	LQT6287LU	TR
11520950CM	LQT6287LU	TR
11522573CM	LQT6287LU	TR
11522574CM	LQT6287LU	TR
11522819CM	LQT6287LU	TR
11522820CM	LQT6287LU	TR
11523285CM	LQT6287LU	TR
11523376CM	LQT6287LU	TR
11523377CM	LQT6287LU	TR
11524865CM	LQT6287LU	TR
11524866CM	LQT6287LU	TR
11525170CM	LQT6287LU	TR
11525171CM	LQT6287LU	TR
11525398CM	LQT6287LU	TR
11525399CM	LQT6287LU	TR
11525997CM	LQT6287LU	TR
11525998CM	LQT6287LU	TR
11525999CM	LQT6287LU	TR
11526404CM	LQT6287LU	TR

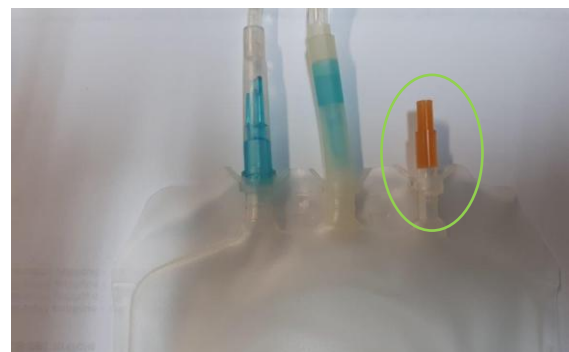
11526405CM	LQT6287LU	TR
11526890CM	LQT6287LU	TR
11527227CM	LQT6287LU	TR
11527228CM	LQT6287LU	TR
11527698CM	LQT6287LU	TR
11527699CM	LQT6287LU	TR
11527700CM	LQT6287LU	TR
11522822CM	LQT716C	DE
11523501CM	LQT716C	DE
11525285CM	LQT716C	DE
11527118CM	LQT716C	DE
11528500CM	LQT716C	DE
11520911CM	LQT747C	DE
11525284CM	LQT747C	DE
11527267CM	LQT747C	DE
11522939CM	LQT748C	DE
11523378CM	LQT748C	DE
11524754CM	LQT748C	DE
11526000CM	LQT748C	DE
11526694CM	LQT748C	DE

**Picture of the device ( LQT610L / LQT612U / LQT6280LU / LQT6281LR) :**

**WITH PLUG ON THE BAG**



*Picture taken of the device in the overwrap*



*Picture of the bag CV1459 with plug*

WITHOUT PLUG (NON-COMPLIANT PRODUCT)



*Picture taken of the device in the overwrap*



*Picture of the bag CV1459 without plug*

Picture of the device ( LQT613E / LQT614E / LQT6287LU / LQT716C / LQT747C / LQT748C):

WITH TWO VISIBLE PLUGS



*Picture taken of the device in the overwrap with two visible plugs: one on the empty bag and one on the bag with the additive solution.*



*Picture taken of the device in the overwrap with only ONE visible plug.*

#### **4. Associated risk & Potential Impact**

- **Severity of the Issue:** Exposure to blood if not detected before use.
- **Possible Consequences:** Lost of blood components if not detected before use.

#### **5. Actions Taken by the Manufacturer**

##### **Corrective and Preventive Actions (CAPA):**

The root cause of the issue has been clearly identified and pertains to a faulty detection measure used in the assembly line. Since 18 November 2024, preventive and corrective actions have been put in place to help prevent the element from being missed.

ANSM has been informed of this Field Safety Notice.

#### **6. Required Actions for Customers / Users**

This defect is easily detectable before use. To avoid the risk of losing the blood product, MacoPharma recommends:

##### **During the Collection step:**

- Before opening or when opening the peelable pouch, check for the presence of the (orange) plug on the red blood cell collection bag for non-leukoreduced blood (see photo above).

During the Processing step:

- Check for the presence of the (orange) plug on the red blood cell collection bag for non-leukoreduced blood before separating blood components on the press.

If the plug is missing, please send the kit to your Materiovigilance Dpt.

- ☒ Check the inventory and identify the affected products.
- ☒ Perform training to concerned staff
- ☒ Complete and return the attached acknowledgment form.
- ☒ If necessary, contact Macopharma representative for further assistance.

Please complete the attached form and return it to the address provided. Please indicate whether further measures are required at your facility. We will then contact you immediately to coordinate further action.

Macopharma is committed to product quality and patient donor and user safety with this forming one of our key pillars as a company. We apologize for any disruption these additional checks may cause within your processes and would like to thank you in advance for your assistance and cooperation in this matter.

We remain available for any questions or clarifications you may have, please do not hesitate to contact us if required.

Best regards,

Béatrice CARVALHO  
Complaints and Vigilance MD Manager  
Correspondant Local de Matérivigilance

Please fill out this form and send it by e-mail before June 2<sup>nd</sup>, 2025, to  
[medicaldevice.vigilance@macopharma.com](mailto:medicaldevice.vigilance@macopharma.com)

Centre name	
Address	
City	
Name	
Function	
Phone	
Batch in your storage	
Quantity in your storage	
Date	
Signature	