FIELD SAFETY NOTICE

LQT614B: LEAKS PLASMA BAG

Macopharma reference: DEV-2023-00222

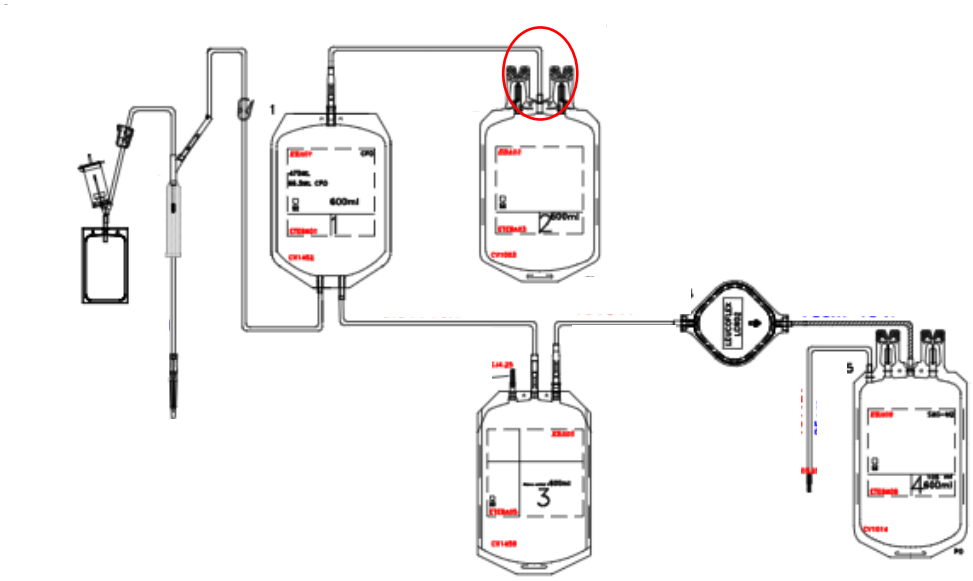
Tourcoing, March 8th, 2023

Dear Sir or Madam,

We would like to inform you that Macopharma has decided to implement a Field Safety Notice for the use of devices LQT614B and NPT611W.

Context:

A customer has reported on the batch 11482320BM reference LQT614B, 35 leaks on the plasma bags detected during processing. These leaks are related to a channel on the central tube (lack of welding).



Traceability of the defective bags (CV1003) highlights a unique day of production (21/12/22) during a specific period of the day and coming from a unique welding machine (A3).

After investigation, we were able to establish that this potential defect concerns batches manufactured in January 2023.

The list of affected batches is as follows:

Customer	PF	Batch	Qty	% risky product
BENELUX	LQT614B	11482811BM	**23130**	3%
BENELUX	LQT614B	11482320BM	**20220**	27%
UK	LQT614B	11481859BM	**14152**	4%
UK	LQT614B	11481176BM	**28231**	1%
KAZAHSTAN	NPT611W	11481139BM	**6135**	66%

Associated risks:

The risk relates to a loss of integrity of plasma bag detectable during customer processing.

Action(s) to be implemented:

With this letter, we are specifically contacting all customers who have received one or more of the affected batches.

These batches will be taken back, and we will recontroled in our facilities to remove the bags from the risky period (percentage of risky period on the table above). Thanks to our visible traceability located on the bottom welding of the bags, we can remove the bags welded during the risky period of the 21/12/2022. The boxes reprocessed will be identified by a green sticker.

Please could you :

- Check the remains stock of the batches listed above,
- Return the completed acknowledgement of receipt to us within 15 days + quantities in stock,
- Quarantine the unused products listed until the return.

Actions undertaken by Macopharma:

All the batches in stock within our warehousing produced during the risky period will be reworked internally prior to distribution.

For batches partially sent to customers, the boxes of the same batches reprocessed internally will be identified by a green sticker, proving that the rework has been carried out on the contents.

The root cause was identified, and the corrective action was implemented.

ANSM has been informed of this Field Safety Notice.

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.

We apologise for any inconvenience this may cause your organisation. Thank you in advance for your support and cooperation.

We remain available for any question you might have,

Best regards,

Béatrice CARVALHO

Complaints and Vigilance MD Manager
Correspondant Local de Matériovigilance

Please fill out this form and send it by e-mail before 22th March 2023 to medicaldevice.vigilance@macopharma.com

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