

FIELD SAFETY NOTICE

SSP+ references: Unable to read batch barcode

Macopharma reference: DEV-2022-01217

ANSM reference: R2233068

Tourcoing, December 12, 2022

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 SSP+.

Context:

Some of our customers have found when using SSP+ products that they cannot read the LOT barcode on the kit label.



After investigation, we were able to establish that this printing defect concerns batches manufactured between July and the beginning of September 2022.

The list of affected batches is as follows:

| References | Batches | Quantities |
|------------|------------|------------|
| SSP2130U | 22072001F1 | 19520 |
| | 22090702F1 | 20040 |
| | 22090601F1 | 19820 |
| SSP2028X | 22090802F1 | 3420 |

| | | |
|-----------------|------------|-------|
| SSP2020U | 22071801F1 | 9930 |
| | 22090503F1 | 28680 |
| SSP2150U | 22090902F1 | 11920 |
| | 22062301F1 | 14780 |
| | 22091201F1 | 13520 |
| | 22091301F1 | 12060 |
| SSP2025U | 22071101F1 | 15960 |
| SSP2030U | 22071301F1 | 20360 |
| | 22072102F1 | 20280 |
| | 22090801F1 | 16840 |
| | 22090901F1 | 20140 |
| SSP2128U | 22071901F1 | 20980 |

Associated risks:

The risk relates to the traceability information associated with the devices.

Failure to read the LOT barcode makes it impossible to record the traceability of the SSP+ solution batch used for customers using the barcode in their system.

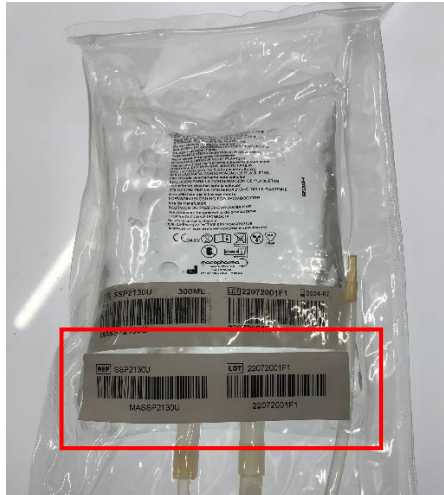
Action(s) to be implemented:

Regarding the lots on the market, if the impossibility of reading the LOT barcodes would constitute a difficulty for the use of the batch, we invite customers to contact the sales manager of the country and we will define the measures to be taken in soon as possible.

Actions undertaken by Macopharma:

All the implicated batched is stock within our warehousing have been reworked by attaching and additional label to the overwrap.

This additional label will ensure the correct LOT barcode is readable for the contained product.



For batches partially sent to customers, the boxes of the same batches reprocessed internally will be identified by a green sticker.

The ANSM (French National Competent Authorities) has been informed of this Field Safety Notice.

Please fill out the attached form, indicating that you have received this FSN and that it's been forwarded to our services.

Thank you in advance for your support and cooperation.

We remain available for any question you might have,

Best regards,

Béatrice CARVALHO

Complaints & Vigilance MD Manager

List of references and batches distributed by country:

| Pays | References | Batches |
|----------------------------------|-------------------|--|
| France | SSP2030U | 22071301F1 22072102F1 |
| Denmark | SSP2150U | 22090902F1 22062301F1 22071301F1 |
| Norway | SSP2150U | 22062301F1 |
| Germany | SSP2150U | 22090902F1 22062301F1 22091201F1 |
| | SSP2030U | 22071301F1 |
| Switzerland | SSP2150U | 22062301F1 |
| Austria | SSP2150U | 22062301F1 |
| Belgium | SSP2128U | 22071901F1 |
| | SSP2150U | 22090902F1 22062301F1 22091201F1 |
| Czech Republic | SSP2150U | 22062301F1 22091201F1 |
| Poland | SSP2150U | 22062301F1 |
| Spain | SSP2128U | 22071901F1 |
| | SSP2150U | 22090902F1 22062301F1 |
| | SSP2030U | 22071301F1 |
| Italy | SSP2030U | 22071301F1 22072102F1 |
| Turkey | SSP2030U | 22072102F1 |
| Australia (Macopharma Australia) | SSP2150U | 22091201F1 |
| Iceland | SSP2030U | 22071301F1 |
| Thailand | SSP2150U | 22062301F1 |



Please fill out this form and send it by e-mail before 31 december 2022 to medicaldevice.vigilance@macopharma.com

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|-------------|--|
| Centre name | |
| Address | |
| City | |
| Name | |
| Function | |
| Phone | |
| Date | |
| Signature | |