SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

SARSTEDT AG & Co. KG · Postfach 12 20 · 51582 Nümbrecht

SARSTEDT AG
Bahnweg Sued
9475
Sevelen

3rd July 2024

Urgent Safety Information

Trade Name:	**REF:**	**Batch:**
S-Monovette® Lithium heparin LH, 4,9 ml, green	04.1936.100	4031821
Type of measure:	Safety note	

Sender: SARSTEDT AG & CO.KG
Sarstedtstr. 1
51588 Nümbrecht

Adressee: User

Affected medical device: S-Monovette® Lithium heparin LH, 4,9 ml
REF: 04.1936.100
Batch: 4031821

Description of the issue:
Due to a production-related error, it is possible that the article S-Monovette® Citrate 9NC 5.4 ml (EU colour code: green, REF: 04.1930.001 LOT: 4031721) is occasionally mixed in the carton of the above-mentioned batch of S-Monovette® Lithium Heparin (ISO colour code: green). The labelling on the product itself is clear and correct, and the functionality of the articles is ensured.

As the two articles mentioned have the same green colour coding for the screw cap and the label, confusion is possible during routine blood sampling. Diagnostic analyses that are carried out as standard with heparinised blood may give

implausible or possibly falsified results due to the preparation containing citrate. The blood sample must be repeated and the analysis carried out again.

Corrective action:
Before using the S-Monovette® Lithium Heparin of the above batch, please check the product labelling to ensure that it is the S-Monovette® Heparin and not the S-Monovette® Citrate. S-Monovette® Heparin and not the S-Monovette® Citrate. If you find S-Monovette® Citrate 9NC 5.4 ml (REF: 04.1930.001 LOT: 4031721), separate it and contact SARSTEDT customer service.

Please complete the attached response form and return it to us at produktrueckruf@sarstedt.com within the next 30 days.

Please keep this information at least until the measure has been completed.

Passing on the safety information:
Please ensure that all affected users of the named products and other parties to be informed are made aware of this urgent safety information. If you have supplied these products to third parties, please forward a copy of this information or inform the contact person listed below.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

Contact person
If you require further information or assistance in this matter, please contact the following people:

For customer specific questions: Your local contact

For product specific questions: Mr. Jochen Roller
Email: marketing@sarstedt.com

SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

SARSTEDT AG & Co. KG · Postfach 12 20 · 51582 Nümbrecht

SARSTEDT endeavours to supply high-quality, safe and effective products at all times. In accordance with our corporate philosophy as a responsible distributor of medical products, we feel it is our duty to take this approach. SARSTEDT regrets the inconvenience this matter may have caused.

If you have any further questions, please do not hesitate to contact your sales representative or customer service representative.

Kind regards

SARSTEDT AG & Co. KG

[redacted]

Jochen Hoffmann
Head of Quality Management

[redacted]

Sebastian Winkels
Head of Customer Service Global

SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

SARSTEDT AG & Co. KG · Postfach 12 20 · 51582 Nümbrecht

Affected deliveries:

Delivery date	pieces	Delivery note	Your order number
13.06.2024	50	1004692	4500241492
18.06.2024	1000	1010401	4500241693
20.06.2024	5000	1013773	4500241829
28.06.2024	7500	1023659	4500242217
22.05.2024	17000	8953711	4500240404
22.05.2024	5000	8953788	4500240653
29.05.2024	500	8958055	4500240788
29.05.2024	5000	8958061	4500240796
05.06.2024	1000	8967318	4500241021
06.06.2024	15900	8969285	4500241119
06.06.2024	5000	8969299	4500241161

SARSTEDT

Geräte und
Verbrauchsmaterial
für Medizin
und Wissenschaft

SARSTEDT AG & Co. KG · Postfach 12 20 · 51582 Nümbrecht

CUSTOMER RESPONSE

*Thank you in advance for supporting SARSTEDT AG & Co. KG with the fulfilment of the legally prescribed obligations to provide evidence**. Please complete this form and send it back to us, preferably by email to**: produktrueckruf@sarstedt.com*

To: SARSTEDT AG&Co.KG

With this response we acknowledge receipt of below mentioned letter

Urgent safety information
Mixing of S-Monovette® Citrate in S-Monovette® Heparin

We further confirm that the corrective action in the aforementioned letter has been read, understood and implemented or will be implemented.

Customer name:	
Address:	
Post code, place:	
Customer number	

Remarks:

_____ _____

Place, date *Signature*